

Public Comments to Safer Consumer Product Regulations

<u>Page No.</u>	<u>Name of Commenter</u>
18	Adhesive & Sealant Council
22	Aerojet-General Corporation
29	Air-Conditioning, Heating & Refrigeration Institute
32	Airlines for America & Boeing
49	Alliance of Automobile Manufacturers*
84	Alliance of Automobile Manufacturers sent by Sierra Research*
110	American Apparel & Footwear Association
117	American Cancer Society Cancer Action Network
119	American Chemistry Council
188	American Cleaning Institute
206	American Coatings Assoc
213	American Forest & Paper Assoc
220	American Wood Council
224	Amway
227	Art & Creative Materials Institute
231	Association of Global Automakers
260	Association of Home Appliance Manufacturers
263	AT & T
266	Attaguile, Faith
267	Auto Aftermarket Industry Association
271	BASF Corporation
273	Battery Council International
280	Bay Area Clean Water Agency
285	BEHR
287	Betancourt Jr. Robert
288	BizNGO
298	BlueGreen Alliance
300	Blyth
302	Breast Cancer Action
303	CA Attractions & Parks Association
305	CA Council for Environmental & Economic Balance
323	CA Department of Public Health
325	CA for a Healthy Green Economy (CHANGE)
355	CA Grocers Association
366	CA Healthcare Institute
370	CA Healthy Nail Salon Collaborative
380	CA Industrial Hygiene Council*
385	CA Manufacturers & Technology Association*
417	CA New Car Dealers Association
442	CA Product Stewardship Council
443	CA Retailers Association
455	CA Stormwater Quality Association
459	CA Travel Association
461	CalChamber*
472	CalRecycle
476	Chemical Industry Council of California

488 Chula Vista Public Works Dept
489 Clean Water Action
492 Clorox Company
496 Complex Durable Goods Coalition*
511 Consumer Healthcare Products Association
517 Consumer Specialty Products Association
553 Cradle to Cradle Products Institute
556 Cradle to Cradle Products Institute 2
558 Creative Nail Design
562 Daimler Trucks North America
566 Defoamer Industry Trade Association
569 Delta Diablo Sanitation District
571 Direct Selling Association
573 Dow Chemical Company
580 Dull, Julie
581 Ecolab
584 Electronic Industry
610 European Semiconductor Industry Association
612 European Union
625 Everall, Patricia
626 Food Packaging Coalition
656 France, Susan
657 Garner, Dylan
658 Gradient
661 Green Chemistry AA Coalition
672 Green Chemistry Alliance
686 Grocery Manufacturers Association
721 Hewlett Packard
748 Hong, Hayley
750 Imperial Valley Resource Management Agency
752 Independent Cosmetic Manufacturers Distribution Association
754 Indie Beauty Network
755 Ingalls, Diane
756 Intel
762 Intelligent Global Pooling Systems Company
768 International Fragrance Association
772 IPC
775 Japan Chemical Industry Association
779 Japanese Government
782 Japanese Industries:
795 Klawans, Becky
796 Koch Industries
799 Lemons, Sheila
800 Levitan, Lynn
801 Levy, Robert
802 Littlejohn, Toni
803 Lorenzen, Nan
804 Mahboubian, Maggie
805 Marin County Hazardous & Solid Waste Mgmt JP
806 Marin Sanitary Service

808 MartzEmerson, Marjorie
814 McKinley, Cameron
815 McMullin, Robyn
816 Mendelson, Roger
817 Metal Fishing Associations
819 Meyer, Amy
820 Mezzavilla, Richard
821 Michelli, Nancy
822 Mikaily, Adit
823 Montgomery, John
824 Montgomery2, John
825 Moran, Marcella
853 MWS Wire Industries
855 National Association of Chemical Distributors
859 National Electrical Manufacturers Association
862 National Shooting Sports Foundation
865 Natural Products Association
869 Newman, Jane
870 Newman, Peter
872 North American Insulation Manufacturers Association
874 North American Metals Council
876 O'Brien, Kevin
877 Palmer, Donald
878 Personal Care Products Council
893 Pharmavite
896 Pierce, Yvonne
897 Plastic Pipe & Fittings Association
899 Plastics Industry Trade Association
902 Plumbing Manufacturers Association
905 PLZ Aeroscience
907 Procter & Gamble
940 Prutzman, Annie
941 Reynolds, Allan
942 Rivera, Alana
943 Rowley, Carol
944 Rubber Manufacturers Association
955 San Benito County Integrated Waste Management Department
956 Santa Barbara County Public Works Dept
957 Semiconductor Industry Association of Korea
959 Sierra Club
964 Sjostrand, Margaret
965 Snow, Andrea
966 SNR Denton
969 Sonoma County Water Agency
971 Speciality Equipment Market Assoc
973 State Water Resources Control Board
978 Stoner Incorporated
980 Taiwan Semiconductor Industry Association
1006 Tapley, Dennis
1007 TDC Environmental

1010 Test Measurement Coalition
1014 Torrance City
1015 Townsley, Rory
1017 Toy Industry Association
1030 Tri-Iso
1033 Tri-TAC
1037 Truck Engine Manufacturers Assoc
1046 UC Berkeley Labor Occupational Health Program
1048 UCLA Sustainable Technology & Policy Program
1055 Unifrax
1076 Unilever
1082 Valasek, Gary
1085 Valero
1090 Vernier, Mary
1091 Vinyl Institute
1092 Warner Babcock Institute*
1097 Water Quality
1099 Western States Petroleum Assoc
1106 W.F. Taylor
1111 Wick, Kristen
1112 Worksafe
1137 Writing Instrument Manufacturers Association

1141 **Form Letters**

Sample/example of 96 letters requesting DTSC to postpone regulation

1 Bade, David
2 Bansal, Mayank
3 Barbalunga, Jonalee
4 Barnaby, Brenda
5 Beaumont, Kaye
6 Bissell, Jacquelyn
7 Bowen, Amber
8 Bracco, Janine
9 Brown, Wes
10 Brunner, Thomas
11 Bufis, Mary
12 Burke, Dan
13 Case, Cindy
14 Chayes, Angelica
15 Cho, Jessica
16 Clark, Scot
17 Corkill, Katherine
18 Crawford, Timothy
19 Csiszar, Steven
20 Dandurand, Curran
21 Delaney, Thelma
22 Dietrich-Ganz, Candy
23 Elgueta, Elias
24 Ferrall, Gina
25 Flacks, Martin

26 Forno, Patrico
27 Fricano, Polly
28 Golin, Julie
29 Gupta, Mukat
30 Guyer, Denis
31 Hamad, Fayez
32 Harand, Harand
33 Hatch, Courtney
34 Heldenfels, Shelley
35 Hellman, Matthew
36 Henrietta, James
37 Hersey, Richard
38 Hill, Beverly
39 Irizarry, Myra
40 Irving, Alexander
41 Johnson, Jared
42 Jones, Cindy
43 Kadosh, Orit
44 Kaegi, Miles
45 Katz, Stanley
46 Kemp, Jamie
47 Lamanno, Margherita
48 Lavinio, Marie
49 LeBeau, Denise
50 Lee, Christine
51 Lee, Grace
52 Libby, Susan
53 Lippmann, Mark
54 Locatell, Pamela
55 Maly, John
56 McCluskey, Vincent
57 Mendelson, Kevin
58 Miles, Anna
59 Mount, Linda
60 Murad, Jeff
61 New, Pam
62 Oconnor, Mary
63 Ornstein, Steve
64 Owen, Patricia
65 Patterson, Tony
66 Peck, April
67 Persons, Richard
68 Pinto, Juan
69 Pruett, Claire
70 Pum, Gregory
71 Rauchwerger, Jerry
72 Reyzis MD, Irene
73 Rhoades, Dean
74 Rivera, Lois
75 Robbins, Patricia

- 76 Ross, William
- 77 Salzano, Marinella
- 78 Schmucker, Patty
- 79 Serruys, Kari
- 80 shah, devyani
- 81 Shargani, Alan
- 82 Sharpe, Bridget
- 83 Sheman, Linda
- 84 Sill, Garth
- 85 Smith, Connie
- 86 Smith, Jill Ann
- 87 Swan, Jennifer
- 88 Tran, Ann
- 89 Tran, Maily
- 90 Veljkovic, Ivana
- 91 Villalobos, Sally
- 92 Waite, Debbie
- 93 Werner, Dan
- 94 Winters, Carri
- 95 Wiseth, Wendy
- 96 Witwit, Ali

1142 **Sample/example of 549 letters supporting the regulation's Chemical of Concern List**

- 1 Abbott, Joanna
- 2 Abraham, Gabe
- 3 Acosta, Alberto
- 4 Acwich, Yael
- 5 Adams, David
- 6 Adams, Michael
- 7 Agostini, Luisa
- 8 Aikawa, Mark
- 9 Alexander, Beverley
- 10 Alvarado, Frank
- 11 Ambra, Leia
- 12 Anderson, Audrey
- 13 Anderson, Clifford
- 14 Anderson, Talaya
- 15 Andrews, Matt
- 16 Anson, Robert
- 17 Apple, Joy
- 18 Attrache, Ghaleb
- 19 Aubrey, Frances
- 20 Ayala, Gloria
- 21 Backer, Hans
- 22 Bailey, John
- 23 Baker, Beth
- 24 Balestreri, Barbara
- 25 Ballard, Nicholas
- 26 Bambery, Richard

27 Barry, Dwight
28 Barton-Paine, Dianne
29 Bass, Jennifer
30 Batallar, Abril
31 Battaglia, Rosemarry
32 Bautista, Ernesto
33 Beal, Jon
34 Bebb, Matthew
35 Becker, Chris
36 Bellak, Nina
37 Beltran, Cathy
38 Benjamin, Elaine
39 Benoit, Diane
40 Beres, Donna
41 Berkers, Jeff
42 Berry, Thomas
43 Bettendof, Lisa
44 Bhalla, Richa
45 Bill, Eileen
46 Billson, Christian
47 Birdsong, Kathy
48 Bithell, Marianne
49 Blakely, Dave
50 Bloom, Brendan
51 Bloomquist, Linda
52 Blossom, Deborah
53 Blunt, Gerry
54 Bob, Michelle
55 Bogin, Ronald
56 BONFIELD, Timothy
57 bonnet, Guillaume
58 Borska, Erika
59 Boskin, Gertrude
60 Boudart, Jan
61 Bower, Rendall
62 Boyd, Ernest
63 Bozzuto, Joe
64 Bradshaw, Catherine
65 Brazier, Helene
66 Broderick, Barbara
67 Brown, Deena
68 Brown, Elliott
69 Bruce, Linda
70 Bruce, Melissa
71 Buckingham, Kim
72 buskirk, Van
73 Caidoy, Krystal
74 Calado, Liesl
75 Calbreath, David
76 Cape, Rown

77 Caputo, Nicole
78 Carlisle, Lindsay
79 Carney, Thom
80 Cattarin, John
81 Cavanaugh, Clay
82 Centurion, Bobboe
83 Chacon, Carol
84 Chambers, Lisa
85 Chandrasekaran, Vidya
86 Chavez, Nola
87 Chen, Jeffrey
88 chen, Tracey
89 Chin, Yvonne
90 Ciarra, Marcella
91 Clark, Jeff
92 Clark, Julie
93 Clark, Thomas
94 Cockle, Justine
95 Cohen, Eleanor
96 Cohen, Howard
97 Connelly, Kristin
98 Conteras, Alma
99 Cook, Craig
100 Corrigan, Sean
101 Costello, James
102 Couch, Charles
103 Courtney, Courtney
104 Cowing, Deborah
105 Cox, Molly
106 Craven, Will
107 Cripe, Teri
108 Cross, Pauline
109 Crow, Steve
110 Dagilis, Danielle
111 Dahl, Pamela
112 Daly, Robert
113 DamHorst, Kris
114 Danis, Susan
115 Dau, Lynn
116 Davila, Lea
117 Davis, Rebecca
118 Decker, Karen
119 Declercq, Tamara
120 Delrahim, Sandra
121 Denton, Deborah
122 Dev, Gita
123 Diaz, Mario
124 Dow, Linda
125 Dreyfus, Stuart
126 Edwards, Allan

127 Ehrke, Erik
128 Eklund, Steve
129 Emanuel, Myra
130 Engels, Thomas
131 Entenman, Richard
132 Ewald, William
133 Farnes, Randy
134 Feldman, M
135 Feldman, Ruth
136 Ferguson, Ezekiel
137 Finney, Barbara
138 Firshein, David
139 Fisher, Evelyn
140 Fleeman, Jeff
141 Flores, Josephine
142 Foss, Chris
143 Foss, Janice
144 Fox, Louis
145 Francis, Lena
146 Frank, Linda
147 Fraser, Alex
148 Friedland-Brown, Karen
149 Fruchey, Kate
150 Fuezy, Jon
151 Gab, Margie
152 Gaitanis, Constantine
153 Gallagher, Kathrun
154 Gallegos, Mark
155 Garcia, Felipe
156 Garcia, Mark
157 Garneau, Paul
158 Garvey, Henry
159 Gatheral, Tracey
160 Gebbie, Peter
161 Gembka, Lori
162 Georgia, Romola
163 Getter, Camile
164 Ghini, Elle
165 Gibb, Wayne
166 Gibbs, Nancy
167 Giddings, Linda
168 Giddings, Ron
169 Gilchrist, Tom
170 Gill, Katherine
171 Gillespie, Rhiannon
172 Gilliam, Jeffrey
173 Gilson, Miriam
174 Goff, Fred
175 Golden, Charlie
176 Golias, Theresa

177 Gonzalez, Katie
178 Gonzalez, Nydia
179 Goodwin, Truss
180 Gorham, Linda
181 Gosman, Amy
182 Gottfried, David
183 Graham-Ramos, Briana
184 Grande, Shari
185 Grave, Philip
186 Graves, Carolyn
187 Graves, Caryn
188 Gray, Ralph
189 Green, Don
190 Green, Tracy
191 Green, Will
192 Grosso, Anthony
193 Gueriera, Daniel
194 Guida, William
195 Guitierrez, Richard
196 Gulassa, Harriet
197 Hadley, Douglas
198 Haenk-Clark, Pam
199 Hagi, Ioana
200 Hagstrom, Earl
201 Halizak, Kimberly
202 Hall, Anthony
203 Hammett, Cindy
204 Hammond, Sue
205 Hanna, Helen
206 Hardbarger, Michel
207 Harmon, Lucille
208 Harper, Darby
209 Hartman, Nancy
210 Hauf, John
211 Hedger, Deb
212 Hedley, Janet
213 Heinze, Aliyah
214 Hendershott, Kurt
215 High, Nicole
216 Hilyer, Lisa
217 Ho, Marjorie
218 Hodder, Mary
219 Hohle, Maggie
220 Holmes, Joseph
221 Holn, Harvey
222 Hong, Dary
223 Hope, John
224 Horsfall, Nathan
225 Houston, Ellie
226 Huang, Hongbin

227 Huang, Janey
228 Hughes, Eric
229 Hunt, Karen
230 Hyde, Karen
231 Ingra, G. Mason
232 Ino, Tiffany
233 Irvin, Katja
234 Jacobson, Rachel
235 Jenkins, Dan
236 Jerome, Jane
237 Johnsen, Brent
238 Johnson, Brandie
239 Johnston, Christina
240 Jones, J. Ray
241 Jones, Janet
242 Jordan, Christian
243 Joseph, Kazimieras
244 K, Patrick
245 Kaluza, Natasha
246 Katell, Katell
247 Kaufmann, Suzanna
248 Kaylor, Steve
249 Kelly, Charlotte
250 Kelly, Nancy
251 Khan, Seema
252 Khouri, Julianne
253 Kidambi, Madhava
254 Kiesling, Nancy
255 Kim, John
256 Kim, Meena
257 Kirby, Kathryn
258 Kirk, John
259 Kosanovic, Bruce
260 Koss, James
261 Kroemer, Harry
262 Kubota, Charleen
263 Kuczynski, Kathleen
264 La Puma, Karen
265 LaBrecque, Charyl
266 Lampman, Joscelyn
267 Landau, Jean-Claude
268 LaNew, Maryann
269 Lavensaler, Kurt
270 LeCount, David
271 Lee, Kathy
272 Lemons, Sheila
273 Leung, Lily
274 Lewis, Patrick
275 Liang, Ming
276 Linderman, Eileen

277 Lish, Christopher
278 Little, Ryan
279 Littlejohn, Will
280 Lockhart, Rebecca
281 Lockwood, Margo
282 Lombard, Ruth
283 Longland, Martiza
284 Lopez, Jimmy
285 Louie, Jo
286 Loustalot, Colin
287 Lucas, Steve
288 Luenow, Brian
289 Luikart, Heather
290 Lum, William
291 Lund, John
292 Lyman, Robert
293 M, Shunay
294 Maas, John
295 Macis, Michelle
296 Mack, Tina
297 Maddox, Terry
298 Mahoney, Dawn
299 Malik, Chinta
300 Mariposa, Virginia
301 Martin, Dalton
302 Martins, Sarah
303 Matson, Melissa
304 McAlister, Christopher
305 McCaig, David
306 McCallister, Gloria
307 McCaughey, John
308 McCool, Mike
309 McCullough, Denali
310 McDaniel, Shannon
311 McDonald, Kristen
312 McGraw, Stepheny
313 McNeely, Rhiannon Gillespie
314 McQuiston, Elizabeth
315 Meldon, Carolyn
316 Melvin, Joseph
317 Messer, Mark
318 Mewhinney, Bruce
319 Mezey, Jennifer
320 Michaels, Dana
321 Mihalovics, Dariko
322 Miller, Abigail
323 Miller, John
324 Miller, Lisa
325 Minault, Kent
326 Mintz, Kevin

327 Miracle, Cindy
328 Misuraca, Melinda
329 Moats, Jasmine
330 Montalvo, Chris
331 Moore, Gailen
332 Morales, Paul
333 Moreau, Jenny
334 Morelli, Randall
335 Moss, Elizabeth
336 Mueller, Barry
337 Murnane, John
338 Murphy, Joanie
339 Murphy, Katie
340 Murphy, Lisa
341 Nattenberg, Edward
342 Nelson, Ted
343 Nice, Robert
344 Nichols, Crystal
345 Nitzan, Ben
346 Nixon, Amy Jane
347 Noe, Lynn
348 Noonan, Robert
349 Norris, Jon
350 O'Connor, Meave
351 Odezynskyj, Maria
352 Oliver, Nancy
353 Olson, Dean
354 Omander, Susanne
355 Oporto, Christopher
356 Ornelas, Karen
357 Ory, Rhona
358 Ostrom, Gavin
359 Padgett, Susan
360 Page, Sydne
361 Paone, Anne
362 Pardini, Jenny
363 Parikh, Mandar
364 Parker, Daniell
365 Parrish, Joan
366 Parrish, Kristoffer
367 Patti, Vincent
368 Peate, R.
369 Pena, Gustavo
370 Perlscy, Alex
371 Petrinovich, L.
372 Phillips, Marilyn
373 Phipps, Connie
374 Pichumani, Ramani
375 Phippen, Karma
376 Pletschet, Fran

377 Porter, Ted
378 Posch, Michael
379 Pounds, James
380 Prado, Rene
381 Pratt, Joe
382 Price, Charlotte
383 Prieto, Maria
384 Rabinowitz, Noel
385 Ramaswamy, Jagaw
386 Ramos, Cynthia
387 Rearden, Chance
388 Reed, Robert
389 Reiff, Shauna
390 Respecke, David
391 Rhodes, Lori
392 Richard, Anne Marie
393 Richard, Cheryl
394 Richter, Steve
395 Rickman, Roz
396 Roachford, Tom
397 Roberts, Les
398 Roberts, Leslie
399 Robie, Lisa
400 Rodocker, Mary
401 Rogers, Mike
402 Rohwedder, Shawn
403 Ross, Zack
404 Round, Lorraine
405 Rowe, Susan
406 Rudinow, Mattie
407 Russell, Teresa
408 Ruth, Carol
409 Rutland-Brown, Wesley
410 Ryan, Irmie
411 Rye, Cameron
412 S, Jeff
413 S, Robert
414 Salamander, Gilad
415 Sanchez, Henry
416 Sanders, Jason
417 Sandoval, Dore
418 Sapkin, Joshua
419 Sarkany, Jen
420 Sato, Nancy
421 Sato, Susan
422 Sawyer, Marvin
423 Saxon, Rolf
424 Scharich, Jeannette
425 Schmidt, Sunshine
426 Schmit, Joe

427 Schroder, Tim
428 Schwalbenberg, Peter
429 Scopazzi, Jennifer
430 Seifert, David
431 Seltzer, Jody
432 Semereaux, Melody
433 Seto, Jeneele
434 Shearer, Julie
435 Sheppard, Patrick
436 Sheridan, Lydia
437 Shiplacoff, David
438 Simms, Ellen
439 Sinclair, Ron
440 Singh, Madhulika
441 Singh, Rayeena
442 Sipan, Carol
443 Sjostrand, Margaret
444 Smelker, James
445 Smith, Glenn
446 Smith, Greg
447 Smith, Isabelle
448 Smith, Lawrence
449 Smith, Nicki
450 Sohn, Jennifer
451 Solari, Noreen
452 Solin, Donna
453 Songster, Jeff
454 Sox-Harris, Lara
455 Spencer, John
456 Spickler, Julie
457 Sprague, Belle
458 Standish, Jennifer
459 Stark, Marilyn
460 Starkweather, CK
461 Stellanova, Tammy
462 Stevens, Eric
463 Strugnell, Ann Christine
464 Suen, Aimee
465 Sultan, Yaldah
466 Sutherland, Megan
467 Sutton, Ellyn
468 Sweek, Tyler
469 Szmcaak, Mark
470 Talbot, Michael
471 Tang, Carol
472 Tarlow, Carol
473 Tatman, Robin
474 Taylor, Leon P.
475 Taylor, Mary
476 Theil, Niki

477 Thompson, Catherine
478 Thurman, Anna
479 Tichman, Nadya
480 Timms, Dana
481 Tokay, Hale
482 Tomaselli, Richard
483 Tompt, Jay
484 Torres, Alicia
485 Tracy, Glen
486 Trahan, Judy
487 Ulam, Jim
488 Ungar, Ruth
489 Up, Fed Coles
490 Usman, Susan
491 Usmani, Ozair
492 Van Kol, Elise
493 Van Sidcu, Michelle
494 Vanapalli, Kishore
495 Vancor, Lisa
496 Vaningen, Chris
497 Vargas, Yessenia
498 Velez, Erin Alden
499 Velicescu, Adrian
500 Venekatram, Saras
501 Vezian, Marc
502 Vidales, Angel
503 Vierra, Steve
504 Vinay, Sharon
505 Vizir, Vitali
506 Von Dehn, Verena
507 Vukic, Vesnar
508 Wahdan, Jo
509 Walker, Aurea
510 Wallin, William
511 Walsh, Dana
512 Warila, Jennifer
513 Warren, Patricia
514 Warrilow, Joanne
515 Watson, Donna
516 Watson, Fran
517 Watson, Mary Lou
518 Wattenberg, Jane
519 Watts, Nancy
520 Weissbuck, Brian
521 Weiss-Lampert, Laura
522 Welch, Heidi
523 Whitman, Jill
524 Whittle, Jeffrey
525 Wiebe, Tobey
526 Williams, Albert

527 Williams, Linda
528 Willis, Kimberly
529 Wilson, Barbara
530 Wilson, David
531 Wilson, Gary
532 Wilson, Jennifer
533 Wimsatt, Casey
534 Wolfs, Saul
535 Woodruff, Toni
536 Woods, Peter
537 Wright, Natalie
538 Wrucke, Robert
539 Wu, Chen
540 Wyckoff, Julia
541 Wyss, Marianne
542 Yamat, Yasmin
543 Yau, Dennis
544 Yoshida, Irene
545 Youabian, Anita
546 Yuen, Genevieve
547 Zerzan, Paula
548 Zhu, Meng
549 Zimmerman, Marjorie

*Attachments to some comments were too large to post. Please send a request to gcregs@dtsc.ca.gov if you wish to view any attachments not posted here



BY EMAIL

October 10, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives regulation Coordinator
Regulation Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 958112-00806

RE: Comments re DTSC's July 27th Draft Regulation for the Safer Consumer Products

The Adhesive and Sealant Council (ASC) is a North American trade association representing 121 manufacturers of adhesives sealants and suppliers of raw materials to the industry. As director of government relations for ASC, I am writing to express our members' continuing concerns with the latest regulatory proposal for the implementation of The Green Chemistry Initiative legislation.

As we have noted in comments to earlier versions of the proposed regulation, ASC, our members and our industry support the concepts of green chemistry as well as the principles of product stewardship which together lead manufacturers to developing new technologies while always keeping in mind public health and environmental impacts. In reviewing the July 27th proposal, ASC recognizes that the Department has made modifications to the earlier proposals, but our industry still remains deeply concerned with many of the underlying precepts that remain in this proposal. It is still the belief of the Council that implementation of this regulation as proposed could lead to companies abandoning California markets or relocating manufacturing facilities to other states.

One of the many ongoing concerns of ASC members is the overly broad definition of consumer product. This continuing approach for defining consumer products will allow for few exceptions and results in almost any product that was bought, sold or leased in California (from the largest building structures to the smallest retail item) to be scrutinized. It is difficult to reconcile the complexity of this approach with the marginal improvement in health and environmental safety it is likely to advance. In addition, full implementation of the regulation as drafted would create such an immense administrative and scientific burden on the DTSC that it will not be feasible for the Agency to implement it.

For regulation to be an effective it needs a definition of consumer product that has focus and direction. A realistic approach would begin with a review of the California Air Resources Board's definition of consumer product as defined in their consumer rule (see <http://www.arb.ca.gov/consprod/regs/2008/3cp.htm>).

“Consumer Product” means a chemically formulated product used by household and institutional consumers including, but not limited to, detergents; cleaning compounds; polishes; floor finishes; cosmetics; personal care products; home, lawn, and garden products; disinfectants; sanitizers; aerosol paints; and automotive specialty products; but does not include other paint products, furniture coatings, or architectural coatings. As used in this article, the term “consumer product” shall also refer to aerosol adhesives, including aerosol adhesives used for consumer, industrial, and commercial uses.

This definition has been utilized by CARB for more than a decade and it provides a manageable scope of that regulation that continues to be lacking in the present draft language.

With regard to the Agency’s most recent proposal that would establish a list of approximately 1200 “Chemicals of Concern” (COC), ASC recognizes the fact that the DTSC is proposing to significantly reduce the number of chemicals from its earlier proposals but unfortunately the effort stops there. This approach remains seriously flawed unless the DTSC undertakes some sort of prioritization process that identifies a discrete subset of the highest priority of the 1200 that should rightly be identified as Chemicals of Concern. No other state, federal or international jurisdiction apart from California has sought to begin with 1200 or more actionable chemicals.

Given the expansiveness of the list, there may be a large number of chemicals that will not come under consideration by the DTSC process for a number of years yet in the interim formulated products containing those chemicals may be implicated as hazardous to consumers simply because of poorly chosen list title. ASC would recommend that the agency begin by identifying their more expansive list of chemicals as “Chemicals Under Consideration.” DTSC should concentrate on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm and substances known to be persistent, bioaccumulative and toxic in the environment as designated by the US EPA and others. This discrete subgroup of chemicals with expected exposures in California should be identified as Chemicals of Concern.

The DTSC’s approach to Alternative Assessments remains extremely open-ended and confusing. For example, the proposed rule states that “the responsible entity shall take into account all projected and direct and indirect cost impacts during the life cycle of the product and the alternatives being considered.” Such an assignment is far too broad and complex of an undertaking for any manufacturer. There is no guidance as to how a manufacturer could estimate all the factors involved or what methodologies and scope could be utilized to deliver useful, reproducible results.

In addition, the establishment of accreditation bodies and assessors is unnecessary and simply will add another cumbersome layer to the process that will simply increase costs by establishing a new regulatory body with training schemes that duplicate well established standardized training.

Another concern with the revised proposal is that it no longer specifies a default concentration based on trigger that determines whether a manufacturer can qualify for an exemption from the Alternative Analysis requirement. Instead, DTSC will specify a threshold for each COC in any Priority Product. Such an arbitrary approach will only further confuse formulators’ understanding of what constitutes a chemical of concern. As an example, such an approach could result in rogue contaminants placing an otherwise benign product

October 10, 2012

Page 3

under scrutiny. There must be a fixed definition of what is de minimus and it must provide that “naturally occurring” contaminants are exempted under any definition.

In addition, leaving a default concentration open-ended for different chemicals and different products will add to the complexity for determining compliance with the regulation and leave manufacturers uncertain to whether they are ever in compliance with regulations.

ASC is supportive of proposal establishing as a “de minimus” level a concentration less than or equal to 0.1%

Finally, ASC and its members continue to be concerned with the continued threat to manufacturers’ vital intellectual property upon which all innovation is based in multiple ways. Any manufacturer whose product may be selected as a “priority product” because it contains a “chemical of concern” are not only obligated to pursue an alternative formula but in addition must also disclose to DTSC how they will develop changes to a product and provide a summary of that to be made available to the public including their competition. In addition, when conducting an alternative analysis a manufacturer can be compelled to identify all chemicals in the current product as well any chemicals involved in alternative product being developed.

Should a manufacturer assert a claim of trade secret protection, the present regulation continues to mandate that they provide DTSC with considerable irrelevant and extraneous information that clearly modifies the legal definition of a trade secret. For example, providing the estimated value of the information to a manufacturing competitor, the estimated amount of effort and/or money expended in developing a new formula, or defense of why chemical identity is not readily discoverable though reverse engineering may not be that easy to calculate and is definitely not within the purview of any regulatory body.

By even asking these type of questions, it appears that the DTSC is setting itself up in the role of judging the value of one company’s innovative approach against another’s. Such an effort is clearly neither the role of government nor the intent of the California Assembly when it passed AB1879.

Ultimately implementation of this regulation could threaten such damage to marketplace in the area of CBI protection that it would be easy to envision many consumer product manufacturers abandoning California markets rather than risk the loss of their intellectual property.

Again ASC and its members appreciate the opportunity to comment on the draft regulation and if there are any questions or need for further explanation of any of these points, please do not hesitate to contact me at 301/986-9700 ext. 112 or mark.collatz@ascouncil.org.

Respectfully Submitted,



Mark Collatz

Director of Government Relations



P O Box 13222
Sacramento CA 95813-6000

Tel: 916-351-8524
Fax: 916-355-3603
william.hvidsten@aerojet.com

William E. Hvidsten
Senior Counsel
Environmental Law

October 5, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Aerojet-General Corporation Comments to Proposed Green Chemistry Regulations

Dear Ms. Von Burg:

Aerojet-General Corporation, a wholly owned subsidiary of GenCorp and headquartered in Sacramento, California, is an aerospace and defense contractor principally serving the missile and space propulsion, and defense and armaments markets. At Aerojet, industry leadership in Sustainability has become "institutionalized" as a vital part of our 70-year old company culture. With the implementation of Aerojet's "Sustainability Initiative," Aerojet's focus on environmental stewardship and corporate responsibility is at the forefront of our everyday business decisions. Aerojet has recently commissioned a six MW solar facility (one of the largest industrial installations of its kind in the U.S. and the largest in California), implemented a web-based system for the company-wide collection and reporting of energy consumption, greenhouse gas emissions (GHG), water use, waste and recycling and is reviewing means by which to reduce the environmental footprint of its fleet vehicles. Under the direction of Aerojet's Sustainability Executive Council, our company is meeting the challenges and opportunities to operate in a cleaner, more sustainable fashion.

The Proposed Regulations Do Not Provide Sufficient Protections for Classified Information Protected by the United States Government

The subject rulemaking activity relative to safer consumer product alternatives (Green Chemistry) may affect Aerojet's operations as a government defense contractor. As a government defense contractor, a significant portion of Aerojet's activities constitute or involve the application of Classified Information protected by the United States Government in the interest of national security. The types of Classified Information may include the ultimate work product, the chemical formulation

of the work product, i.e. a propellant, and the technology and processes used to manufacture that work product. Unlike most civilian goods and services regulated by the Department of Commerce or comparable state agency, military defense services, technical data and defense articles are subject to a whole host of dictates, demands and restrictions regarding the disclosure and handling of Classified Information or other information protected from disclosure on the basis of national security. A brief summary of the protections required for Classified Information is provided below. A more detailed summary is provided on Appendix 1.

Only the United States Government may Authorize Disclosure of Classified Information

A defense contractor neither determines whether information is classified nor makes the determination to declassify such information. The authority for those determinations resides with the United States Government. Similarly, the United States controls the authorized disclosure of Classified Information, including the person or persons authorized to receive the information. Defense contractors are subject to significant sanctions for unauthorized disclosure of Classified Information. For information that is not deemed as classified, but still constitutes defense related technical data protected under the International Traffic in Arms Regulations (ITAR), the Department must determine whether it and its personnel are authorized to receive such information and ensure that such information does not become accessible to anyone who is not a United States citizen or a foreign national with a valid permanent resident (“green card”) status. ITAR further prohibits disclosure of defense related technical data to any non-resident foreign national in the United States. Failure to adequately protect such defense related technical data may subject Department personnel to sanctions.

Trade Secret Protections are not Sufficient to Protect Classified Information

The proposed Green Chemistry regulations do not provide the means by which to address the mandatory prohibitions against providing Classified Information to the Department. Article 10 articulates the process by which the Department will handle information that is subject to trade secret protection, confidentiality, privilege or other form of exemption from public disclosure. The process, however, only addresses the prohibitions against the Department disclosing protected information. Article 10 presumes the information will come into the hands of the Department and then specifies the protections necessary to prevent public disclosure. It does not address situations where the defense contractor is prohibited or otherwise restricted from disclosing such information to the Department.

Legislative and Regulatory Changes are Needed to Protect Classified Information

Aerojet urges the Department to seek legislative changes to create an additional exemption for this type of information. In the interim, modifications to the proposed regulations are needed to address the obligations of the government defense contractor when requested to provide information that may be classified or otherwise protected on the basis of national security. The Department should also modify the proposed regulations in a way that clearly spells out the manner in which the Department will review and handle any information that is classified or otherwise protected on national security grounds. Absent such modifications, a preemption issue arises from the direct conflict between the

federal requirements for the protection of national security and those requirements to produce information pursuant to the Green Chemistry regulations.

The Proposed Regulations may Conflict with Government Defense Contract Specifications

The regulations as proposed may also present an unintended conflict with government defense contract specifications. Modification of those contract specifications may or may not be possible. Propulsive formulations are often derived over decades and their chemical components are inflexible. Government specified formulations are also often fixed and inflexible. Once a formulation is qualified, replacement chemicals cannot be substituted without a lengthy and complex re-engineering and requalification process or a reformulation may simply not be technically feasible. The proposed regulations do not provide an adequate process that recognizes what may be inflexible requirements of the United States Government in the manufacture of goods utilized for national defense purposes.

Proposed Modifications

Aerojet's proposed modifications to the regulations addressing the production and handling of Classified Information are also provided below.

Purpose: To recognize the potential conflict that arises when a defense contractor is required to provide Classified Information to the Department.

Add new subsection (a)(21) to Section 69501.1- Classified Information means information owned by, produced by or for, or is under the control of the United States Government, the unauthorized disclosure of which could reasonably be expected to result in identifiable or describable damage to the national security and as more further defined in Presidential Executive Order 13526.

Add subsection (b)(3) to Section 69501.2 as follows- Classified Information Notification. A responsible entity that is a manufacturer of a product is not responsible for complying with the applicable requirements of this chapter if the manufacturer provides a written notice to the Department containing information demonstrating to the Department's satisfaction that the product is subject to any federal requirement relating to Classified Information or other limitations on the basis of national security. The notice should be provided no later than the due date for compliance with this requirement. The notice must contain all of the following information:

- (A) The name of and contact information for the manufacturer;
- (B) A statement signed by the owner, or an officer of the company, or an authorized representative certifying that the information constitutes Classified Information or is subject to limitations on the basis of national security.
- (C) A brief description of the nature of the information to the extent such information does not constitute Classified Information or information subject to limitations on the basis of national security; and
- (D) The name and contact information for the United States Government Official authorized to determine the eligibility for access to Classified Information or information subject to limitations on the basis of national security.

Aerojet-General Corporation Comments
Proposed Green Chemistry Regulations
October 5, 2012
Page 4

Aerojet is pleased to be able to submit these comments and would be happy to assist the Department in formulating adequate protections for information vital to national security.

Very truly yours,

A handwritten signature in black ink, appearing to read "William E. Hvidsten". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

William E. Hvidsten

cc: Chris Conley
John Bobis

APPENDIX 1

SUMMARY OF PROTECTIONS REQUIRED FOR CLASSIFIED INFORMATION

Executive Order 13526

Executive Order 13526 (effective January 5, 2010) sets forth the bases for determining and ultimate handling of classified data generated by the U.S. Government and government contractors. Among the protected information are weapons systems and scientific and technological data related to national security. (Section 1.4) Section 4.1 of the Executive Order provides the basis for determining an individual is authorized to receive classified information. A person may have access to classified information only if she/he has received a favorable determination of eligibility for access by a federal agency director or his/her designee; the person has signed an approved non-disclosure agreement; and the person has a need to know the information. The person must also receive required training regarding the safeguarding of classified information and the criminal, civil, and administrative sanctions that may be imposed on an individual who fails to protect classified information from unauthorized disclosure. United States officers and employees and government contractors, among others, are subject to sanctions for disclosure to unauthorized individuals of information properly classified under this order or predecessor orders. Sanctions include termination of classification authority and loss or denial of access to classified information. (Section 5.5)

National Industrial Security Program

Aerojet is subject to the Department of Defense Directive 5220.22, "National Industrial Security Program" (NISP). The National Industrial Security Program Operating Manual (NISPOM), reissued on February 28, 2006, prescribes the requirements, restrictions and other safeguards to prevent unauthorized disclosure of classified information. The NISPOM controls the authorized disclosure of classified information in the possession of contractors of the U.S. Government. The manual implements applicable federal statutes, executive orders, national directives, international treaties and certain government-to-government agreements.

Classification and Declassification. As set forth in Executive Order 13526, a classification decision can only be made by a U.S. Government official. The contractor does not have the authority to make the decision to declassify information. NISPOM makes clear that downgrading or declassifying actions must be based on a directed action such as a Contract Security Classification Specification or upon formal notification by the Government Contracting Authority. (Section 4-107)

Disclosure of Classified Information. In general, contractors must ensure that classified information is disclosed only to persons authorized to receive such information. (Section 5-500) Disclosure of classified information to a contractor's employees is limited to those employees who have a need to know for the performance of their specific tasks and services. (Section 5-501) Although NISPOM does not address disclosure of classified information to state and local agencies, disclosure of such information to other federal agencies is prohibited unless specifically authorized by the agency that has classification jurisdiction over the information. (Section 5-506) Public disclosure of classified information or unclassified information pertaining to a classified contract is prohibited absent prior review and clearance specified in the Contract Security Classification Specification or by the Government Contracting Authority. (Section 5-511).

Reproduction and Transmission of Classified Information. NISPOM imposes similar restraints on the reproduction, physical delivery and electronic transmission of classified material. Reproduction of TOP SECRET documents other than in the preparation of a contract deliverable requires the consent of the Government Contracting Authority. Reproduction of SECRET and CONFIDENTIAL documents are subject to limited circumstances. The Cognizant Security Agency is responsible for accrediting automated information systems used to process classified information in industry. (Section 5-601; 5-400; 5-401-404; and Section 8) Posting classified or other confidential information on the Department's website, as proposed in Section 69301.7, would clearly run afoul of these obligations.

Authorized Access to Classified Information. Access to classified information requires personnel security clearances. The Cognizant Security Agency determines the eligibility for access to classified information in accordance with the national standards. The contractor is required to limit requests for personnel security clearances necessary for operational efficiency. The establishment of "pools" of cleared employees is prohibited. (Section 2-200) Contractors, such as Aerojet, are not permitted to grant security clearances. (Section 2-206)

International Traffic in Arms Regulations

Disclosure of Defense Related Technical Data. Exports of military defense services, technical data and defense articles are subject to detailed licensing requirements on design, marketing and demonstration activities prior to sale and permanent export. These requirements are found in the International Traffic in Arms Regulations ("ITAR") 22 C.F.R. § 120 *et seq.* ITAR's application extends to explosives, energetic materials, propellants, including, but not limited to perchlorates and hydrazine, and pyrotechnics and specially formulated fuels for aircraft, missile and naval applications. ITAR further prohibits disclosure of

defense related technical data to any non-resident foreign national in the United States.

Verification of Eligibility. Prior to receiving any protected documents subject to ITAR regulation, the Department would have to verify that it is eligible to receive such information. Department personnel or other persons who may have access to the defense related technical data must be United States citizens or foreign nationals with a valid permanent resident (“green card”) status. Those individuals, in turn, must comply with the ITAR regulations in general and the disclosure restrictions. Foreign national employees who do not require such access must be segregated from all ITAR-controlled technical data, and internal polices and controls must be in place to prevent any unauthorized access.

Violations. Incidental or unintended access by a foreign national is a violation of the ITAR and may subject the individual disclosing the information to substantial penalties and even criminal enforcement actions. Any requirement that Aerojet or any other holder of a license for export of military defense services, technical data and defense articles, without adequate assurance from the Department that the information will not be accessible to unauthorized persons, subjects them to civil or administrative penalties, potential criminal enforcement action or even debarment from further export activity. Similarly, the Department’s employees who do not prevent such access may also be subject to penalty. See 22 CFR §§ 127.1 (b) and (d) and 127.7.

October 11, 2012

Krycia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: AHRI Comments – Safer Consumer Products Proposed Regulations

Dear Ms. Von Burg:

These comments are submitted by the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) in response to the proposed regulations on safer consumer products issued by the California Department of Toxic Substances Control (DTSC) in July 2012.

AHRI is the trade association representing manufacturers of heating, cooling, water heating, and commercial refrigeration equipment including manufacturers of commercial HVAC pumps. More than 300 members strong, AHRI is an internationally recognized advocate for the industry, and develops standards for and certifies the performance of many of the products manufactured by our members. In North America, the annual output of the HVACR industry is worth more than \$20 billion. In the United States alone, our members employ approximately 130,000 people, and support some 800,000 dealers, contractors and technicians.

We believe that as written, the proposed regulations create an uncertain regulatory environment for our industry since the chemicals of concern (COC) and the priority products lists will not be published until after the effective date of the regulations. We view the COC and the priority product lists as being essential pieces of the safer consumer products regulations. The proposed regulations also provide DTSC with limitless discretionary authority over a process that will be used to regulate consumer products, thereby eliminating virtually any certainty that a business might have in terms of regulatory treatment once the COC and the priority product lists are published. It will be nearly impossible for manufacturers to design compliant products since compliance is an ever-shifting target under the proposed regulations. It would be difficult for our industry to keep track of an expansive COC list, especially if the list lacks a prioritization process. Rather than targeting thousands of chemicals at once, the DTSC should focus its efforts on targeting chemicals that pose the greatest hazard. The priority product list should be based on scientifically valid criteria that clearly outline how DTSC identified the priority products. The process of developing the priority product list should focus on intentionally-added chemicals in products and reasonable and foreseeable exposure to those chemicals.

The proposed regulations require that the responsible entity submit the preliminary alternatives analysis (AA) report no later than 180 days after the date the product is listed on DTSC's final priority products list. Additionally, the responsible entity is required to submit the final AA report no later than 12 months after the DTSC issues a notice of compliance for

the preliminary AA report. We believe that the 180-day and the 12-month submission deadlines are too stringent given the fact that our industry not only has to face the uncertainty with respect to the COC and priority product lists but may also have to allocate a significant amount of time and resources to develop viable solutions that comply with the proposed regulations.

§ 69501.5.(b)(F)(6) of the proposed regulations indicates that a list of all preliminary AA reports and final AA reports will be posted on DTSC's website. Such language has the potential of publicizing a manufacturer's future production plans, thereby impeding innovation and competition, and could expose industry participants to liability under applicable federal antitrust laws. Hence, the proposed regulations should be amended to clarify that any information designated by a manufacturer to be a "Trade Secret" shall not be included on DTSC's website.

When addressing regulatory duplication, the proposed regulations state that DTSC may exempt a product that is regulated by other federal or state regulatory programs, or international trade agreements. The recognition of duplicative regulations is absolutely essential in the required prioritization process that will determine what chemicals and products will be subject to the safer consumer products regulations. Our industry is already subject to several regulations that are issued by various federal and state regulatory bodies. Some of these regulatory bodies are:

- U.S. Environmental Protection Agency (EPA)
- U.S. Department of Energy (DOE)
- California Energy Commission (CEC)
- South Coast Air Quality Management District (SCAQMD)
- California Air Resources Board

We recommend that DTSC account for the regulations issued by the organizations mentioned above in order to avoid placing an unnecessary burden on our industry through regulatory duplication. Regulatory duplication for any product should be a straightforward question – is the potential health or environmental impact from the chemical in the product regulated by another agency or not? Where that is the case, by definition any action by DTSC would be regulatory duplication and should be avoided. As an example, § 69501.1.(a)(3) of the proposed regulations defines greenhouse gases like hydrofluorocarbons (HFCs), nitrogen oxides and nitrous oxides (NOx) as air contaminants that have adverse impacts on air quality. The proposed regulations state that these “contaminants” have the ability to result in adverse public health and have ecological, soil, or water impacts. On what basis did the department include this language in the proposed regulations? What research study provides a basis for classifying greenhouse gases as air contaminants? Additionally, the fact that this section lists various greenhouse gases suggests that DTSC has not yet accounted for the existing federal and state regulations on greenhouse gases. HFCs are currently regulated by the EPA and have never been classified by EPA as air pollutants. On October 30, 2009, EPA published a final rule with respect to the mandatory reporting of greenhouse gases that requires the reporting of annual emissions of certain HFCs ([74 FR 56260](#)). On March 12, 2004, EPA issued a final rule on venting and sales of refrigerant substitutes ([69 FR 11946](#)). The rule sustains the Clean Air Act prohibition against venting HFCs. DTSC should recognize EPA's efforts with respect to HFCs and remove all references to HFCs from the safer consumer products proposed regulations, so that unnecessary regulatory duplication can be avoided.

AHRI appreciates the opportunity to provide these comments. If you have any questions regarding this submission, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to be 'AR' with a flourish underneath.

Aniruddh Roy
Regulatory Engineer
Air-Conditioning, Heating, and Refrigeration Institute
2111 Wilson Boulevard, Suite 500
Arlington, VA 22201-3001, USA
Phone 703-600-0383
Fax 703-562-1942
aroy@ahrinet.org



Airlines for America™
We Connect the World



October 11, 2012

Submitted Via Email:

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

RE: Comments on Proposed Safer Consumer Products Regulations (Proposed New Chapter 55, division 4.5 of Title 22, California Code of Regulations)

Department Reference Number: R-2011-02

Office of Administrative Law Notice File Number: Z-2012-0717-04

To Whom It May Concern:

Airlines for America ("A4A") and The Boeing Company appreciate this opportunity to submit comments on the Department of Toxic Substances Control ("DTSC")'s proposed Safer Consumer Products Regulations ("proposed regulations"). A4A is the principal trade and service organization of the U.S. airline industry.¹ Its member airlines and their affiliates transport more than 90 percent of all U.S. airline passenger and cargo traffic.

The Boeing Company is the world's leading aerospace company and the largest manufacturer of commercial jetliners and military aircraft combined. Additionally, Boeing designs and manufactures rotorcraft, electronic and defense systems, missiles, satellites, launch vehicles and advanced information and communication systems. The company also provides numerous military and commercial airline support services.

A4A, its members, and Boeing take environmental protection seriously and we have a strong record of advancing environmental protection within our operations and throughout our respective supply chains. Our achievement has largely been the result of a relentless commitment to innovation and efficiency improvement, a commitment that extends to the green chemistry arena. Accordingly, we generally support the goals of this regulatory initiative.

¹ The members of A4A are: Alaska Airlines, Inc., American Airlines, Inc., Atlas Air, Inc., Delta Air Lines, Inc., Federal Express Corporation, Hawaiian Airlines, JetBlue Airways Corp., Southwest Airlines Co., United Airlines, Inc., United Parcel Service Co., and US Airways, Inc. Air Canada is an associate member.

Like all regulatory schemes, however, the proposed regulations must be structured to mesh with the existing legal structure governing aviation. The defining characteristic of our industry is that safety is our core mission and cannot be compromised. To help ensure the safety of air transportation, the Federal Aviation Administration ("FAA") was granted exclusive authority to specify the requirements under which U.S. aircraft and aircraft components are approved, aircraft maintenance is performed, and aircraft are operated. Aircraft operators are required by law to operate under these strict controls and attempts by states to regulate aircraft operations have consistently been struck down by the courts under the doctrine of federal preemption.²

It also is critical to understand the importance of aviation to the California economy and the nation as a whole. The FAA reports that commercial aviation is ultimately responsible for 4.9 to 5.2 percent of U.S. gross domestic product ("GDP") and helps generate \$1.2 to \$1.3 trillion in annual economic activity, \$370 to \$405 billion in annual personal earnings and 9.7 to 10.5 million jobs.³ Aviation is even more important to the California economy:

- In 2009, aviation drove 4.8% of California's GDP and accounted for about 1.1 million jobs, about 5.5% of total employment in the state.⁴
- "[In 2008, a]cross all states, a total value of \$562.1 billion in goods was transported by air. California ranked highest with \$101.4 billion [or, 18% of the national total]."⁵
- "[In 2008, t]he value of domestic air freight from California accounts for about one-fifth of the value all domestic shipments, or \$39 billion."⁶
- According to U.S. Department of Commerce, nearly half of all exports from California are shipped by air. Together, California imports and exports shipped by air were valued at over \$160 billion in 2011 (about \$440 million per day).⁷
- Within the State of California, Boeing is the largest manufacturer with about 21,000 employees.

² Courts have consistently held the Federal Aviation Act of 1958 creates a "uniform and exclusive system of federal regulation" of aircraft that preempts state and local regulation. *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); see also *American Airlines v. Department of Transp.*, 202 F.3d 788, 801 (5th Cir. 2000) (aviation regulation is an area where "[f]ederal control is intensive and exclusive") (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 3030 (1944)). This pervasive federal regulatory scheme extends not only to aircraft in flight, but also to aircraft-related operations on the ground. In addition, the Airline Deregulation Act ("ADA") precludes states from "enact[ing] or enforce[ing] a law, regulation, or other provision having the force and effect of law related to a price, route or service." 49 U.S.C. § 41713(b)(1).

³ FAA, *The Economic Impact of Civil Aviation on the U.S. Economy* (August 2011), available at: http://www.faa.gov/air_traffic/publications/media/FAA_Economic_Impact_Rpt_2011.pdf.

⁴ *Id.* at p. 8.

⁵ *Id.* at p. 40.

⁶ *Id.*

⁷ Percentages are based on value of shipments. See U.S. Dept. of Commerce, International Trade Administration State Import Data (<http://tse.export.gov/stateimports/TSIREports.aspx?DATA=>) and State Export Data (<http://tse.export.gov/TSE/TSEReports.aspx?DATA=SED>).



Airlines for America™

We Connect the World



- Boeing has about 4,100 suppliers/vendors, supporting an estimated 200,000 direct and indirect jobs. The goods and services purchased from these suppliers/vendors are worth more than \$6.8 billion to the California economy.
- Boeing also has more than 56,000 retirees in the state and contributed more than \$11.3 million to California charities.⁸

We understand that the purpose of the present regulatory proposal is to establish a structure for future regulation. It is difficult to assess the ultimate impact of such a scheme, for example, before the chemicals of concern and priority products are determined. However, ensuring that essential considerations are built into the structure of the regulation from the beginning is vital to the long-term viability of this regulation. Most fundamentally, this means recognizing safety is the aviation industry's overriding imperative⁹ and the limits of the State's authority under federal law.

I. Executive Summary

As discussed in greater detail below, the proposed regulations are preempted as applied to aviation. Courts have long held that the Federal Aviation Administration Authorization Act ("FAA Act") and its implementing regulations create a "uniform and exclusive system of federal regulation" of aviation safety that preempts state and local regulation.¹⁰ Further, the Airline Deregulation Act ("ADA") expressly prohibits states from enacting or enforcing any law related to a "price, route, or service" of an air carrier.

We therefore request that DTSC, consistent with its authorizing legislation¹¹ and its stated intent to avoid "duplicat[ion of] or conflict with existing federal law"¹²: (1) acknowledge in the final regulations, or in the rulemaking record, that the State is precluded from regulating

⁸ Based on 2011 annual data.

⁹ For example, General Electric recently discovered that their decision to use a new, lower lead coating on certain jet engines caused cracks on the engine shafts. *See Cracks Spur Board to Urge Check of Dreamliner Engines*, N.Y. Times, Sept. 14, 2012. Reports indicate that the coatings were intended to keep moisture off the threads of the engine shaft, however, the lower-lead coating had actually sealed in moisture, which weakened the steel when it came under pressure. <http://www.nytimes.com/2012/09/15/business/national-transportation-safety-board-urges-frequent-inspections-of-ge-engines.html> As a result, several 787s were removed from service and/or had their engines replaced until the cracking could be corrected, potentially affecting rates, routes, and services.

¹⁰ *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); *see also American Airlines v. Department of Transp.*, 202 F.3d 788, 801 (5th Cir. 2000) (aviation regulation is an area where "[f]ederal control is intensive and exclusive") (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 3030 (1944)).

¹¹ California Health & Safety Code § 25257.1(b) ("This article does not authorize the Department to supersede the regulatory authority of any other department or agency.")

¹² Initial Statement of Reasons ("ISOR") for the California Green Chemistry Proposed Safer Consumer Product Alternative Regulations (R-2010-05) at p. 10.

aviation; (2) acknowledge that the State cannot identify products used to maintain, service, or repair aircraft and related equipment as "priority products"; and, (3) revise specified definitions and operative provisions in the proposed regulations accordingly, as set forth herein.

II. As Reinforced by its Authorizing Legislation, DTSC is Preempted from Regulating Aviation.

DTSC has stated that it does not intend to promulgate regulations that "duplicate or conflict with federal law,"¹³ a statement which is entirely consistent with California Health & Safety Code section 25257.1(b). This section specifies that the statutory article "does not authorize the department to supersede the regulatory authority of any other department or agency." To act within the authority conferred under the California Green Chemistry legislation and consistent with federal law, it is critical to understand the preemptive effect of federal law. It is particularly important with respect to the aviation industry.

A. The FAA Act preempts the entire field of aviation safety.¹⁴

The FAA Act provides that "[t]he United States Government has exclusive sovereignty of airspace of the United States."¹⁵ The principal objectives of the FAA Act are to promote safety and efficiency and the development of air commerce.¹⁶ To achieve the statutory purposes of the FAA Act, Congress provided extensive and plenary authority to the FAA to implement these

¹³ ISOR at p. 10.

¹⁴ Article VI of the United States Constitution provides that the laws of the United States "shall be the supreme law of the land . . . anything in the constitution or laws of any state to the contrary notwithstanding." Federal law may supersede state law in several different ways. Congress may preempt state law through express statutory terms or "express preemption." *Jones v. Rath Packing Company*, 430 U.S. 519, 525 (1977). Alternatively, Congressional intent to preempt state law in a particular field may be inferred from a scheme of federal regulation "so pervasive as to make reasonable the inference that Congress left no room for the State to supplement it," and where the state law touches a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. *Pacific Gas and Electric v. State Energy Resources Conservation & Development Commission*, 461 U.S. 190, 203-204 (1983). This is known as field preemption. In areas where Congress has not completely displaced state regulation, federal law may nonetheless preempt state law to the extent it conflicts with federal law, either because compliance with both federal law and state regulations is "a physical impossibility" (*Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963)) or because the state law stands "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). This is known as conflict preemption. In addition to preemption, the Commerce Clause of the U.S. Constitution places limits on the amount of regulatory control that DTSC may exert over commerce that takes place wholly outside the state. See *CTS Corp. v. Dynamics Corp. of America*, 481 U.S. 69, 88-89 (1987); see also *Healy v. Beer Inst.*, 491 U.S. 324, 336 (1989). To the extent that the proposed regulations had the practical effect of controlling conduct beyond the boundaries of the State (e.g., the design, manufacture, or operation of aircraft out of state and/or the purchase and use of chemicals in out-of-state operations for aircraft that may operate in California), these could unduly burden interstate commerce.

¹⁵ 49 U.S.C. § 40103(a).

¹⁶ 49 U.S.C. § 40101 *et seq.*



Airlines for America™
We Connect the World



objectives.¹⁷ The FAA has exercised this authority by promulgating regulations that broadly regulate aircraft and passenger safety.¹⁸ This extensive body of federal regulation leaves no room for states to establish or impose aircraft or passenger safety requirements different than or in addition to the federal requirements. In *Montalvo v. Spirit Airlines*, the Ninth Circuit Court of Appeals held, “[T]he FAA preempts the entire field of aviation safety through implied field preemption. The FAA and regulations promulgated pursuant to it establish complete and thorough safety standards for air travel, which are **not subject to supplementation by, or variation among, state laws.**”¹⁹

In *City of Burbank v. Lockheed Air Terminal*, the Supreme Court ruled that the FAA Act preempted local regulations that intruded upon the free flow of aircraft on the ground and in the air.²⁰ The Court concluded that under the FAA Act, “the delicate balance between safety and efficiency . . . and the protection of persons on the ground” imposed by federal aviation law “requires a uniform and exclusive system of federal regulation if the congressional objectives underlying the Federal Aviation Act are to be fulfilled.”²¹ The pervasive nature of this scheme of federal regulation led the Court to conclude that Congress had intended to fully preempt the field of aircraft operations. According to the Court:

Federal control is intensive and exclusive. Planes do not wander about in the sky like vagrant clouds. They move only by federal permission, subject to federal inspection, in the hands of federally certified personnel and under an intricate system of federal commands.²²

Courts have consistently adopted this preemption model to invalidate or limit state laws regulating aircraft operation, including laws that were not specifically directed at aviation, but which nonetheless regulated aircraft flights indirectly.²³

¹⁷ See, e.g., 49 U.S.C. §§ 40103, 44502, and 44721.

¹⁸ See e.g., 14 C.F.R. Parts 21 (certification procedures for products and parts), 25 (airworthiness standards: transport category airplanes), 33 (airworthiness standards: aircraft engines), 39 (airworthiness directives), 43 (maintenance, preventative maintenance, rebuilding, and alteration), 61 (certification: pilots, flight instructors, and ground instructors), 63 (certification: flight crewmembers other than pilots), 65 (certification: airmen other than flight crewmembers), 91 (general operating and flight rules), 119 (certification: air carriers and commercial operators), 121 (operating requirements: domestic, flag, and supplemental operations), 145 (repair stations).

¹⁹ *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007) (emphasis added).

²⁰ *City of Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973).

²¹ *Id.*

²² *Id.* at 633-34 (quoting *Northwest Airlines, Inc. v. Minnesota*, 322 U.S. 292, 303 (1944) (Jackson, J., concurring)).

²³ E.g., *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007); *U.S. Airways, Inc. v. O'Donnell*, 627 F.3d 1318, 1326 (10th Cir.2010); *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 795 (6th

FAA oversees every aspect of aircraft design, engineering, and maintenance, approves aircraft design and requires certification aircraft meet approved design and establishes stringent mandates governing ongoing maintenance and modification of aircraft. FAA regulations establish detailed requirements applicable to virtually every part and product used on or in the maintenance of aircraft that can take the form of performance standards applicable to parts and products used on aircraft.²⁴ Requirements in FAA regulations can also specify or limit the use of certain chemicals.²⁵ The point is that FAA has plainly preempted the field and DTSC is precluded from issuing "supplementing" regulations; DTSC retains no authority to act in this sphere, even if the FAA has not acted to regulate a specific chemical or product.

Preemption applies in the aviation context even where the FAA has not specifically addressed the issue targeted under state law. For example, in *Montalvo*, the court held that plaintiffs could not maintain negligence claims against the airlines for their alleged failure to warn passengers of the risks of developing deep vein thrombosis, because, even though FAA regulations do not address such risks, federal law preempts the entire field of aviation safety. Similarly, DTSC is preempted from regulating aviation safety under the proposed regulations, related to reducing consumer exposure to chemicals from products, even if federal requirements do not relate to the precise issues covered in the regulations. In the present context, preemption of State authority to regulate the use of certain chemicals or products used in aircraft or aircraft maintenance does not depend on the presence of federal regulations that specifically address chemicals or products.²⁶

Cir.2005); *Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 367-68 (3d Cir.1999); *French v. Pan Am Express, Inc.*, 869 F.2d 1, 5 (1st Cir.1989).

²⁴ E.g., 14 CFR 25.735(b)(2) (requiring "[f]luid lost from a brake hydraulic system following failure . . . is insufficient to cause or support a hazardous fire on the ground or in flight"); 14 CFR 25.733(e) (requiring "wheels must be inflated with dry nitrogen or other gases shown to be inert so the gas mixture in the tire does not contain oxygen in excess of 5 percent by volume"); 14 CFR Part 25, Appendix F (detailing fire resistance standards applicable to a wide variety of aircraft parts, including interior ceiling and wall panels, floor covering, textiles, seat cushions, padding, decorative and non-decorative coated fabrics, leather, trays, galley furnishings, partitions, galley structure, large cabinet walls, structural flooring, electrical conduit, air ducting, joint and edge covering, clear plastic windows and signs, materials used in the construction of stowage compartments, etc.)

²⁵ E.g., 76 Fed. Reg. 77367-69 (requiring use of "alodined rub strips").

²⁶ Even in the tort context, an area of law traditionally within the police powers of the states, courts have recognized that the FAA Act preempts state standards of care relating to aviation safety. E.g., *Abdulla*, 181 F.3d at 371 (finding that even when there is no specific federal provision or regulation governing air safety, the general standard of care in FAA Act regulations prohibiting the "careless or reckless" operation of an aircraft preempts "any state or territorial standards of care relating to aviation safety") (emphasis in original); *Curtin v. Port Authority of New York*, 183 F. Supp. 2d 664, 668-671 (S.D.N.Y. 2002) (finding that the standard of care in a negligence action relating to aviation safety is a matter of federal, not state, law given that FAA Act regulations set out a "general standard of care" for the aviation industry supplemented by "an array of specific safety standards").



Airlines for America
We Connect the World



B. The ADA expressly preempts any state regulation that significantly impacts airline rates, routes, or services.

In addition to implied field preemption under the FAA Act, the ADA expressly prohibits states from enacting or enforcing any law "related to a price, route, or service of an air carrier."²⁷ The U.S. Supreme Court has interpreted the term "related to" broadly to preempt all state laws that have "a connection with or reference to" airline prices, routes, or services.²⁸ In *Morales v. Trans World Airlines, Inc.*, the Supreme Court found that a state's enforcement of fare advertising guidelines was preempted as applied to airline fare advertising because the obligations imposed by the guidelines severely burdened the airlines' ability to place restrictions on lower priced seats and to advertise lower fares.²⁹ The *Morales* decision made clear that a state law need not expressly address the airline industry or be specifically designed to affect it; as long as the law has a connection with airline prices, routes or services, preemption of the law is mandated under the ADA.³⁰

In *Rowe v. N.H. Motor Transportation Association*, the Supreme Court recently reaffirmed *Morales* and its broad interpretation of ADA preemption.³¹ The state law at issue sought to compel tobacco retailers to use a "delivery service" that provided certain assurances about the recipients of the tobacco purchases. The Supreme Court held in *Rowe* that: (1) state laws "having a connection with, or reference to carrier rates, routes, or services are pre-empted"; (2) "such pre-emption may occur even if a state law's effect on rates, routes or services is only indirect"; (3) "it makes no difference whether a state law is consistent or inconsistent with federal regulation"; and (4) "pre-emption occurs at least where state laws have a 'significant impact' related to Congress' deregulatory and pre-emption-related objectives."³²

III. Consistent with its Authorizing Legislation, DTSC May Not Regulate Aviation as Contemplated by the Proposed Regulations.

Given the "intensive and exclusive" federal control noted above, DTSC cannot apply the proposed regulations to aviation because federal law preempts the entire field of aviation safety.³³

²⁷ 49 U.S.C. § 41713(b)(1).

²⁸ *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992).

²⁹ *Id.* at 388-90.

³⁰ *Id.* at 386.

³¹ *Rowe v. N.H. Motor Transp. Ass'n*, 128 S. Ct. 989 (U.S. 2008).

³² *Id.* at 995 (internal quotation marks omitted).

³³ In contrast to conflict preemption, which applies only to the extent that a state law conflicts with federal law or stands in the way of effectuating the purpose of the federal law, field preemption applies

A. Preemption applies to aircraft and operation of aircraft.

To the extent that the proposed regulations could regulate aircraft owned or operated by the airlines or sale by airlines of air transportation services as "consumer products," they would be plainly preempted. In particular, the proposed regulations could be interpreted as authorizing the imposition (in certain circumstances specified in § 69506.5) of restrictions on the settings in which a product may be sold or used, the form in which a product may be sold, who may purchase or use a product, and "any other use restriction" that reduces the amount of chemicals of concern in the product or reduces the ability of the product to cause an exposure.

Any restrictions on chemicals or materials in aircraft used by airlines to transport passengers would require airlines to cease routing aircraft containing these chemicals into the state, a result that would clearly have a significant impact on rates, routes and services, as well as aircraft operations. As such, the ADA would preempt the proposed regulation due to its direct relation to airline prices, routes or services³⁴ and under the FAA Act due to its impermissible encroachment into or supplementation of FAA's regulation of aircraft operations and safety.

B. Preemption applies to aircraft parts and components and aircraft maintenance.

The FAA, exercising its exclusive jurisdiction over aircraft safety, certifies aircraft and aircraft components. In order to operate a U.S. registered aircraft in any airspace, FAA requires that the aircraft maintain an Airworthiness Certificate.³⁵ As one part of maintaining certification, an aircraft must comply with all applicable Airworthiness Directives ("ADs") that FAA adopts over the aircraft's service life.³⁶ ADs are rules issued by FAA that direct actions necessary to ensure that aircraft remain at or above their certified level of safety. The ADs prescribe specific inspections, repairs, modifications, maintenance, and/or operating procedures.³⁷ Airworthiness Directives, including referenced manufacturer Service Bulletins or Instructions for Continued Airworthiness ("ICAs"), are explicit regarding the actions to be performed and materials to be used.³⁸ ADs address the full range of aircraft parts and

more broadly based on the inference that Congress intended to occupy the entire field at the exclusion of state regulation in the same area.

³⁴ In the present context, air transportation is a service, not a product.

³⁵ To obtain and maintain an airworthiness certificate, the operator must ensure that the configuration of the aircraft, including all related products or articles, are consistent with the FAA-approved specifications. See FAA Order No. 8130.2G, sections 200(a) and 4002(a) (Aug. 31, 2010).

³⁶ See *id.* at section 4002(a)(9).

³⁷ See FAA database of Current Airworthiness Directives by Make, available at [http://rgl.faa.gov/Regulatory and Guidance Library/rgAD.nsf/Frameset?OpenPage](http://rgl.faa.gov/Regulatory%20and%20Guidance%20Library/rgAD.nsf/Frameset?OpenPage).

³⁸ *Id.* An ICA is a manual or set of manuals that a manufacturer must provide along with an aircraft, aircraft part, or other associated product. ICAs must include servicing information with instructions covering topics including, but not limited to, servicing parts, task capacities, types of fluid to be used, applicable pressures for the various systems, access panels for inspection and servicing, lubrication points, and types of lubricants to be used.



Airlines for America

We Connect the World



components, from aircraft engines and skins to aircraft furnishings, insulation, and coffee makers.³⁹

To the extent the proposed regulations would impede the use of products necessary or mandated for aircraft maintenance and safety, the regulations would also be preempted under the ADA as an impermissible state law relating to prices, routes or services.⁴⁰ The U.S. Supreme Court has concluded that where a state law has a "significant impact" on airline prices, routes or services, it is preempted under the ADA, even if the law is not specifically designed to affect the airline industry and has only an indirect effect on prices, routes or services.⁴¹

The airlines must be able to maintain access to spare parts, supplies, and other materials that support the safe flight and operation of aircraft. Under FAA regulations, airlines are required to have these items available at all points along their service route as necessary for the proper servicing, maintenance, and preventative maintenance of airplanes and auxiliary equipment.⁴² Interruptions to airlines' access to, use of, or price paid for service and maintenance products resulting from state regulation would impact the airlines' ability to offer required service in California. Hence, any regulation which may impair the airlines' ability to procure materials needed to perform required service, or which has the effect of driving costs of said items up, is expressly preempted by the ADA.⁴³

Given federal preemption in the field of aviation safety, preemption of state regulations affecting routes, rates and services, and the clear limitation on the Department's rulemaking authority under Section 25257.1(b), we respectfully request that DTSC:

(1) Provide a categorical exemption for aviation:

- a. Exclude "federally certified products" from the definition of consumer product by adding the following language:

§ 69501.1(a)(22)(D) "Consumer product" or "Product" does not mean a "federally certified product."

And,

§ 69501.1(a)(XX) "Federally certified product" means:

³⁹ See FAA database of Current Airworthiness Directives.

⁴⁰ *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992).

⁴¹ *Rowe at 364; Morales at 390.*

⁴² See e.g., 14 CFR §121.105.

⁴³ Regulation that prohibits or makes it more challenging to perform non-essential aircraft maintenance in California also has the effect of moving these operations, and associated jobs, out of state.

- i. A product manufactured in accordance with a design certified or approved by the Federal Aviation Administration or the Department of Defense;
 - ii. A product that is used as a replacement part or component of a product identified in (a); or
 - iii. A product identified in a federally certified program or procedure for the repair or maintenance of a product identified in (a) or (b).
- b. Add new language to the final regulation recognizing the limitations on DTSC's authority to impose requirements related to aviation safety. Specifically, section 69501 should be revised as follows:

§ 69501. Purpose and Applicability.

...

(b)(1) Except as provided in paragraphs (2) ~~and~~, (3), and (4), this chapter applies to all consumer products placed into the stream of commerce in California.

... (4) this chapter does not apply to any consumer product that is required to be certified or approved for such use by the Federal Aviation Administration or the Department of Defense.

- c. Include language in the Final Statement of Reasons ("FSOR") acknowledging Supreme Court and Ninth Circuit Court of Appeals precedent on federal preemption of the field of aviation safety.⁴⁴
 - d. Include language in the FSOR acknowledging that the ADA expressly preempts state laws that relate to airline rates, routes, or services.⁴⁵
- (2) Clarify that the Regulations Cannot Apply to Operation of Aircraft or the Sale of Air Transportation Services.

In the absence of a categorical exemption applicable to aviation, DTSC must at least confirm that air transportation services and aircraft used to provide same are not "consumer products" within the scope of the Safer Consumer Products Regulations, by adding the following language to section 69501.1:

§ 69501.1(a)(22)(X). "Consumer product" or "Product" does not include (i) the sale of transportation services, such as transportation by air, vessel, vehicle, or rail; or the aircraft, vessel, vehicle, or train used by a service provider to provide such transportation.

In the absence of a categorical exemption applicable to aviation, DTSC also must clarify that aircraft operators would not be considered "importers" of aircraft based on their operation and movement of aircraft across borders for the purpose of providing transportation services, and that aircraft operators would not be considered "importers" of products (e.g., replacement

⁴⁴ See e.g., *Burbank v. Lockheed Air Terminal, Inc.*, 411 U.S. 624, 639 (1973); *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007).

⁴⁵ See 49 U.S.C. § 41713(b)(1).



Airlines for America
We Connect the World



parts or maintenance supplies for aircraft and associated equipment) for use in its own workplaces when the operator does not sell or distribute these products to "consumers." Specifically, we respectfully request that DTSC revise Section 69501.1(a)(35), as follows:

§ 69501.1(a)(35) "Import" means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce. "Import" includes reimporting a consumer product manufactured or processed, in whole or in part, in the United States. Aircraft (or any aircraft part or component), vessels, vehicles, and other equipment are not "imported" if they cross borders incidental to, or for the purpose of, providing transportation services. ...

If aircraft were considered to be within the scope of consumer products, the change above is necessary. Otherwise, nearly every aircraft operator would be an "importer" and hence, responsible party with regard to the aircraft in its fleet, simply by virtue of crossing U.S. borders in connection with provision of air transportation services. If the above language is not included in the final regulation as requested above, DTSC should at least explain in the FSOR that the operation of aircraft into or out of the United States would not constitute the "import" of such aircraft, nor would it constitute "import" of any part or component thereof.

Similarly, we respectfully request that DTSC include the following sentence at the end of Section 69501.1(a)(35):

A person does not become an importer for purposes of these regulations, by importing products only for use in its own workplaces, and not to sell or distribute to consumers.

As noted previously, FAA requires airlines to have certain parts and supplies in stock at each repair facility and available for use at any airport for unscheduled maintenance activities. If aviation were regulated under the proposed regulations, the revision shown above is necessary; otherwise, an airline would become an importer, and hence a responsible party, with respect to products which it is mandated by law to keep in stock for use by its employees or contractors in servicing the aircraft.

(3) DTSC Must Require Consideration of the Preemptive Effect of Federal Law in the Determination of Priority Products.⁴⁶

Specifically, sections 69503.2(a)(3) and 69501.1 should be revised as follows:

⁴⁶ The proposed regulation does not take account of field preemption or express preemption. Proposed section 69503.2(a)(3) requires DTSC to consider only the extent to which federal requirements "address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product." This proposed language does not consider that under both field and express preemption, state action may be preempted even if federal regulation does not address the same issues or impacts that are targeted by the state regulation. See sections II (A) and (B), above, and FN 14.

§ 69503.2(a)(3) Other Regulatory Programs. The Department shall consider the scope of other California and federal laws, and international agreements with the force of domestic law, under which the product or the Chemical(s) of Concern in the product is/are regulated, and the extent to which these other regulatory programs (A) preempt the regulation of the product; (B) impose specifications or certification requirements on the product; (C) are subject to requirements related to classified information and information subject to limitations on the basis of national security; and/or, (D) address, and provide adequate protections with respect to the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product. The Department shall not identify any "federally certified product" as a "priority product."

§ 69501.1(a)(XX) "Federally Certified Product" means:

- a) A product manufactured in accordance with a design certified or approved by the Federal Aviation Administration or the Department of Defense;
- b) A product that is used as a replacement part or component of a product identified in (a); or
- c) A product identified in a federally certified program or procedure for the repair or maintenance of a product identified in (a) or (b).

IV. Additional Clarifications Needed in the Regulations

Irrespective of DTSC's views on federal preemption, the following additional issues need to be resolved regarding functional acceptability, public safety, and the definitions for the terms "manufacture," "retailer," "functionally acceptable" and "technically and economically feasible" alternatives.

- A. DTSC should revise proposed Section 69501.1(a)(40)⁴⁷-(41) to clarify that aircraft operators would not be considered "manufacturers" of aircraft based on their repair or installation of standardized components on aircraft (even if such action resulted in the addition/replenishment or increased concentration of a chemical of concern).⁴⁸

⁴⁷ Proposed section 69501.1(a)(40) defines "manufacture" to mean make, produce, or assemble. The section goes on to explain that "manufacture" does not include (A) repair or refurbishment of an existing consumer product, (B) installation of standardized components to an existing consumer product, or, (C) making non-material alterations to an existing consumer product, *unless* the action results in the addition, or increased concentration, or a Chemical of Concern, or replacement of a Chemical of Concern, in a product. (Emphasis added.)

⁴⁸ The FAA certifies aircraft and mandates specific repair and preventative aircraft maintenance procedures. Operators do not have a choice regarding whether to do aircraft maintenance or repairs, nor do they have a choice regarding the materials with which these procedures are performed. Hence, it does not make sense to classify operators as "manufacturers" based on performance of required duties, particularly since they do not have the freedom to modify protocols for existing aircraft, nor do they have the ability to adopt alternative aircraft designs.



Airlines for America
We Connect the World



Specifically, we respectfully request that DTSC remove the qualifying language from the definition of "manufacture" in section 69501.1(a)(40), as follows:

§ 69501.1(a)(40) "Manufacture" means to make, produce, or assemble. Manufacture does not include any of the following actions, ~~unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:~~

- (A) Repair or refurbishment of an existing consumer product;
- (B) Installation of standardized components to an existing consumer product; or
- (C) Making non-material alterations to an existing consumer product.

The Initial Statement of Reasons ("ISOR") accompanying the proposed regulation discusses the intent of the exclusion of repair, refurbishment, replacement parts, and alterations from the definition of "manufacture" as follows: "Existing products, especially durable goods, may need to have replacement parts available for service, repair and maintenance. By allowing these three exclusions, repair and maintenance of existing products can continue without the involvement of this regulatory program." We agree with the sentiment of this provision.⁴⁹

However, the addition of language that would make repair, refurbishment, installation of replacement parts, or non-material alterations fall into the "manufacture" category if they "result[ed] in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern" is extremely problematic. This language could effectively render the exclusions without effect. For example, under this modified definition, an aircraft operator's use of a maintenance product containing a chemical of concern to perform mandatory maintenance could potentially render the operator a "manufacturer" of aircraft. This result is inconsistent with DTSC's stated intent in the ISOR.

- B. DTSC should revise proposed Section 69501.1(a)(55) to clarify that "retailer" does not include a person who purchases products (e.g., replacement parts or maintenance supplies) for use in its own workplaces and who does not sell or distribute these products to "consumers."**

Specifically, we respectfully request that DTSC revise section 69501.1(a)(55), as follows:

§ 69501.1(a)(56) "Retailer" means a person to whom a consumer product is delivered or sold for purposes of sale or distribution by the person to a consumer. "Retailer" does not include a person to whom a product is delivered or sold for purposes of use by the person or one of their employees or contractors, if the product will not be sold or distributed to customers.

As referenced above, aircraft operators are mandated to keep specified service, repair, and maintenance products on hand for use by their repair technicians. If there is not a provision

⁴⁹ ISOR at 28-29.

to address this, airlines would be considered "retailers" for all of the products they are required to stock in order to meet federal requirements.

- C. DTSC should revise proposed Sections 69501.1(a)(31), 69505.4(a)(2)(B)(3), and 69506(a) to clarify the meaning of "functionally acceptable" and include consideration of functional acceptability in the Alternatives Analysis and Regulatory Response Sections.**

Specifically, we respectfully request that DTSC revise sections 69501.1(a)(31), 69505.4(a)(2)(B)(3), and 69506(a) as follows:

§ 69501.1(a)(31) "Functionally acceptable" means that an alternative product meets ~~both~~ all of the following requirements:

- (A) The product complies with all applicable legal requirements;
- (B) ~~The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace~~
The product is compliant with all applicable safety standards and regulatory approval or certification requirements in the relevant industry;
- (C) The product meets other product criteria applicable to the specific nature of the product, including but not limited to: durability; and functional performance; and
- (D) The product would not create significant administrative or other burdens on the Department, the responsible entities, the product end-users, or the public including difficulty in regulatory enforcement.

§ 69505.4(a)(2)(B)(3) A determination of whether a functionally acceptable and "technically and economically feasible alternative" exists.

§ 69506(a) The Department shall identify and require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are functionally acceptable and technically and economically feasible.

- D. DTSC should revise proposed Section 69501.1(59) to clarify the meaning of "technically and economically feasible alternative."**

Specifically, we respectfully request that DTSC revise section 69501.1(59) as follows:

(59) "Technically and economically feasible alternative" means an alternative product or chemical for which:

- (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period;
~~and~~
- (B) The manufacturer's operating margin is not significantly reduced; and
- (C) There is not an associated material increase in consumer or business costs.



Airlines for America
We Connect the World



- E. DTSC should revise proposed Section 69506.6(d)(2)(A) to include consideration of safety in the analysis of product sales prohibitions.**

Specifically, we respectfully request that DTSC revise Section 69506.6(d)(2)(A) as follows:

§ 69506.6(d)(2)(A) The overall beneficial public safety, health, economic, societal, and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and ...

The reason for this modification is that we believe that before the DTSC decides to ban or otherwise restrict a product that the DTSC should consider the purpose the product services and the potential broader impacts that would be caused by regulating the product. For example, restrictions could result in certain businesses needing to relocate outside of the State in order to conduct needed maintenance or a product may serve a broader safety or societal benefit that should be considered before deciding to restrict a product for which a safer alternative does not exist.

V. Economic Impacts

- A. Regulatory action by DTSC, such as listing a Priority Product, requires DTSC to comply with California Administrative Procedure Act requirements.**

The California Administrative Procedure Act ("APA") requires that any agency proposing to adopt, amend, or repeal any administration assess the potential for adverse economic impacts on California business enterprises and individuals. The current proposal largely avoids the issue of economic impacts based on DTSC's assertion that these impacts cannot be quantified until the initial list of Priority Products is released.⁵⁰ If this is the case, we ask that DTSC commit to revisiting the economic impact issues when taking subsequent action, including but not limited to listing Priority Products.

Waiting until the alternatives assessment or regulatory response phases to consider economic aspects of the regulation is not acceptable. The listing of a Priority Product is a form of rulemaking, and as such, DTSC will be operating under APA rulemaking requirements.⁵¹ The APA specifies that:

⁵⁰ See e.g., ISOR at p. 4 ("DTSC has determined that until the initial list of Priority Products is released that it cannot quantify the number of jobs that may be created or eliminated") and Attachment to the Economic and Fiscal Impact Statement (Std. Form 399) ("The 'Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products' does not include an estimate of the costs of the SCP regulations....It is not possible to estimate the costs to businesses and individuals until implementation is under way").

⁵¹ Every "regulation" is subject to the rulemaking procedures of the APA unless expressly exempted by statute. California Government Code § 11346. California Government Code section 11342.600 defines "regulation" as "every rule, regulation, order, or standard of general application or the amendment,

[A]ssessing the potential for adverse economic impact shall require agencies... to adhere to the following requirements ...

(1) The proposed adoption, amendment, or repeal of a regulation shall be based on adequate information concerning the need for, and *consequences of, proposed governmental action.*

(2) The state agency, prior to submitting a proposal to adopt, amend, or repeal a regulation to the office, shall consider the proposal's impact on business, with consideration of industries affected including the ability of California businesses to compete with businesses in other states. For purposes of evaluating the impact on the ability of California businesses to compete with businesses in other states, *an agency shall consider, but not be limited to, information supplied by interested parties.*⁵²

We respectfully request DTSC's acknowledgement that it will comply with APA requirements (including, but not limited to analysis of economic impacts)⁵³ when identifying Chemicals of Concern, Priority Products, Alternatives Analysis Thresholds, and Regulatory Responses.

We also request that in DTSC's consideration of economic feasibility, the Department look broadly, not just at manufacturers of Priority Products, but also on economic impacts felt by other businesses and individuals. Many businesses, including A4A member airlines and Boeing, would be significantly impacted if prices of products used or sold by the business increased or if product relied upon by a business were no longer distributed in California. This request is consistent with the proposed changes to section 69501.1(59) shown in section IV(D), above.

VI. Conclusion

For the reasons outlined above, the proposed regulations are preempted to the extent they would: (1) overlap with aviation safety (a field occupied at the federal level by the FAA); and/or, (2) regulate airline prices, routes, or services (directly or indirectly). We respectfully request that DTSC recognize the unique character of the aviation sector and reflect that recognition appropriately in the final regulations and rulemaking record. We also respectfully

supplement, or revision of any rule, regulation, order or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure."

⁵² California Government Code §11346.3(a)(1)-(2) (emphasis added).

⁵³ While it appears in some respect that DTSC intends to follow notice and comment procedures for each stage of implementation, it is less clear whether DTSC intends to meet all applicable APA requirements. For example, there are several statements in the ISOR which seem to indicate that rather than responding to all comments submitted as part of the Priority Products rulemaking, DTSC will look for latitude to determine which comments warrant a response. See e.g. ISOR at 103 and 158. Under the APA, on the other hand, an agency is required to address each comment received, so long as it is directed at the agency's proposed action or to the procedures followed by the agency in proposing or adopting the action. See CA Govt. Code § 11346.9(a)(3).



Airlines for America™
We Connect the World



request that DTSC consider our comments regarding safety and economic considerations, and suggested clarifications to certain definitions in the proposed regulation.

Thank you for your consideration.

Sincerely yours,

Timothy A. Pohle
Sr. Managing Director
Environmental Affairs
Airlines for America

Michael A. Beasley
Sr. Environmental Specialist
Enterprise EHS Strategy Policy Analysis
The Boeing Company



October 11, 2012

VIA EMAIL
gcregs@dtsc.ca.gov

VIA MAIL
Kryisia Von Burg, Regulations Coordinator
Regulations Section
P.O. Box 806
Sacramento, CA 95812-2806

Re: Comments on July 27, 2012, Draft Safer Consumer Product
Alternatives Regulations

Dear Ms. Von Burg:

On behalf of the Alliance of Automobile Manufacturers ("Alliance"), I am pleased to submit the following comments in response to the latest draft of the Department of Toxic Substances Control's ("Department" or "DTSC") Safer Consumer Product regulations (the "July 2012 Proposal"). The Alliance is a trade association of 12 car and light truck manufacturers, consisting of BMW Group, Chrysler Group LLC, Ford Motor Company, General Motors Company, Jaguar Land Rover, Mazda North America, Mercedes-Benz USA, Mitsubishi Motors, Porsche Cars North America, Toyota Motor North America, Inc., Volkswagen Group of America, and Volvo Cars of North America. As indicated in prior letters, the Alliance appreciates the complexity of the task at hand, and the efforts put forth to date in preparing the July 2012 Proposal. The Alliance embraces the goals and vision for safer consumer products embodied in California's Green Chemistry Statute (the "Statute").

Although it is apparent from the July 2012 Proposal that the Department has considered some of the many comments made by the Alliance and other concerned industry groups, the July 2012 Proposal remains unworkable. Without extensive changes to the draft regulations, the Department will be frustrated in its inability to implement them, industry will be facing compliance uncertainty, and the Statute's goals will be thwarted.

Moreover, a full environmental impact and multimedia assessment of the rulemaking, together with a robust Alternatives Analysis (“AA”) and full economic analysis of all feasible alternatives, is necessary in order for the DTSC to comply with the Statute, the Administrative Procedures Act (“APA”) and the California Environmental Quality Act (“CEQA”).

The Alliance submitted extensive comments on all prior versions of draft regulations, and hereby incorporates each of its previous comments by reference in this letter.¹ Throughout the regulatory development process, the Alliance has consistently advocated for revisions that will render the Green Chemistry Regulations more effective, efficient and expedient, while maximizing the potential for environmental benefits envisioned by the Statute.

I. EXECUTIVE SUMMARY

The Alliance has five major concerns with the July 2012 Proposal:

1. **Violation of Health and Safety Code § 25257.1**

Health and Safety Code § 25257.1 prohibits the Department from adopting regulations which limit, duplicate, and/or conflict with the regulatory authority of other departments or agencies. The July 2012 Proposal does not comply with § 25257.1; instead, it purports to allow the Department to “consider” other regulatory programs as it implements its own rules. This language falls short of the clear statutory directive to avoid duplicative or conflicting regulations and puts the Department in the position of evaluating whether the rules of other agencies “provide adequate protections” with respect to any issues of concern to the Department. The rules should be changed to provide a blanket exemption for products already regulated under existing schemes, including automobiles and their components.

2. **Violation of Due Process: The July 2012 Proposal Does Not Comply with Fundamental Requirements of the Administrative Procedure Act**

The July 2012 Proposal sets in motion a piecemeal process whereby the details of regulatory requirements will be developed through an evolving series of vaguely described processes, including the posting of lists, work plans, and other “guidance” on the Department’s website. These yet-to-be-developed documents will have a major impact on the actual tasks that the regulated community will be expected to perform in carrying out the requirements of the July 2012 Proposal, including the requirement to undertake the critical AAs that are the heart of July 2012 Proposal. All such documents should be subjected to the APA notice-and-comment process before they are finalized. Otherwise, the public and the regulated community will not have sufficient information to understand the full scope of the program, which is necessary in order to provide meaningful and thorough comments. The Department has a legal duty to expose all aspects of its regulatory program to public comment; it may not relegate key elements to some uncertain, piecemeal, future process conducted without APA compliance.

¹ Attachment C to this letter is an index of all previous Auto Alliance comments. We also incorporate by reference the exhaustive comments submitted by the Durable Products Coalition, European Union, TechAmerica, American Chemistry Council, Consumer Specialty Products Association, California Chamber of Commerce, California Foundation for Commerce and Education, and ICF International.

3. The July 2012 Proposal Is Not Supported By Required Economic Impact Analysis

The APA requires that a certain set of basic information be provided as a means to allowing stakeholders to understand how proposed regulations will impact the economy, businesses and consumers. The Department has not complied with this requirement. The Department claims that the July 2012 Proposal is too general, vague and open-ended for it to be able to identify how business would be impacted. While we share the Department's concern about the overbreadth and vagueness of the proposed rules, this does not excuse the Department from the requirement to comply with its statutory duties. Government Code § 11346.3(a) requires that state agencies proposing to adopt regulations assess the potential for adverse economic impacts on California businesses and individuals. It requires that a state agency "consider the proposal's impact on business, with consideration of industries affected including the ability of California businesses to compete with businesses in other states." Cal. Gov. Code § 11346.3(a)(2). The agency should prepare an "economic impact analysis that assesses whether and to what extent" the regulation will affect: creation or elimination of jobs in California, creation or elimination of existing businesses in California, the expansion of businesses currently doing business in California, and the benefits of the regulation to the health and welfare of Californians. *Id.* at § 11346.3(b).

4. Violation of CEQA

CEQA requires the preparation of a program Environmental Impact Report ("EIR") prior to adoption of the proposed regulations. The Statute's requirement that a multi-media analysis be prepared unless it is conclusively determined that there is no potential for a significant adverse effect on public health or the environment is a tacit, if not express, recognition of the real potential that adoption of Green Chemistry Regulations could result in significant environmental impacts.

Instead of preparing a programmatic EIR or the necessary multi-media analysis, the Department relies on a Notice of Exemption which alternatively asserts a statutory and categorical exemption to which it is not legally entitled. It is critically necessary for the Department to conduct a programmatic analysis now, so that it can make any modifications to the July 2012 Proposal that are necessary to address potentially significant environmental impacts and can analyze reasonable and feasible alternatives to specific provisions of the July 2012 Proposal - or the July 2012 Proposal as a whole - before the regulations are adopted and enforced.

DTSC attempts to limit the scope of the environmental review required by CEQA to the Department's own administrative activities, thereby ignoring any "reasonably foreseeable" activities that might occur as a result of the Department adopting the July 2012 Proposal. DTSC implies that the "project" consists merely of DTSC's "intellectual evaluation and analysis" (i.e., Department employees administering the program in an office environment). However, in its Economic Analysis, its Initial Statement of Reasons and in public statements, the Department states that it anticipates a growth in green business and overall growth in jobs. The Department also asserts that having a large list of Chemicals of Concern ("COCs") will serve as a signal to

the market to switch out of these chemicals to other product ingredients. If these potential changes are reasonably foreseeable enough to justify the purported economic benefits of the July 2012 Proposal, then the potential impacts of said changes must be analyzed under CEQA and in the multimedia analysis that is required under the Statute.

5. Other Substantive Problems with the July 2012 Proposal

A typical automobile has about 30,000 parts, and most individual parts are themselves composed of multiple materials. Each major automaker works with a global network of more than 1,000 suppliers. Automakers track over 2,500 substances in a common data system at a 0.1% level which has resulted in over 304 million data sheets and 100,000 system users. While DTSC acknowledges the complexity of automobiles in its inclusion of the concept of “highly durable products,” the proposed regulatory steps and structure do not accommodate the unique considerations of such products.

The July 2012 Proposal also fails to acknowledge the steps that automakers and suppliers are already taking to identify substances of concern and impose engineering standards that restrict the use of such substances and prevent regrettable substitutions. This system, now in place for more than a decade, is already a well-established tool for identifying substances of concern and imposing engineering standards that restrict the use of substances of concern and prevent regrettable substitutions.

Finally, the July 12 proposal fails to address the potential for conflict with the stringent performance, quality, reliability and safety standards that automakers must meet.

In light of the complexity of our products, we have the following concerns with respect to the workability of the July 2012 Proposal:

A. Chemical Scope

As the Alliance has stated repeatedly throughout the regulatory development process, the July 2012 Proposal, similar to all previous proposals, does not set forth an achievable scope of chemicals to be regulated. Although the Statute specifically calls for chemical prioritization, the July 2012 Proposal does not prioritize. Instead, it calls for an initial COC list of up to 1,200 chemicals and contemplates addressing trace amounts of chemicals (below the 0.1% level). The scope of chemicals to be regulated is simply not practical, meaningful or legally defensible.

Of particular concern is the DTSC’s plan to include in this list certain naturally occurring contaminants and contaminants from recycled materials. DTSC’s interpretation therefore completely dis-incentivizes automotive recycling (e.g., steel) and further discourages the use of recycled metals and plastics out of concern of likely untraceable and inconsequential levels of naturally occurring and historic trace materials.

B. Product Scope

The Alliance applauds the Department’s decision to limit the initial scope of products regulated under the July 2012 Proposal. That said, the definition of “component” remains vague,

allowing for complex assemblies such as engines to be the subject of an alternative analysis. Additionally, the petition process provided for in Article 4 of the July 2012 Proposal (and only recently added to the regulatory scheme) enables the regulation of an endless scope of products from day one, irrespective of whether said products are on the initial Priority Products list published by the Department. Given the gravity of the task before the Department, the scope of products to be regulated must be further refined.

C. Reporting Scope

Put simply, the July 2012 Proposal requires too much from both the Department and industry. The current draft of the regulations sets forth unworkable reporting obligations that implicate enormously high compliance costs, and which will require unprecedented amounts of Department manpower. Examples include the multiplicity of notifications and open-ended data requests. Moreover, it requires the submittal of information that is unnecessary and the submittal of which could compromise valuable trade secrets and stifle innovation. Prior to adoption, the scope of reporting under the July 2012 Proposal must be refined.

D. Regulatory Response Scheme

The July 2012 Proposal sets forth multiple regulatory responses that can be undertaken by the Department. While some of these potential responses are expressly provided for under the Statute, many are not. In addition, many would be overly burdensome for both the Department and industry, and some raise potential conflicts with existing regulatory schemes. These are discussed in some detail below but include the labeling and end of life requirements. The regulatory response scheme set forth in the July 2012 Proposal requires further consideration and revision prior to adoption of the regulations.

II. LEGAL DEFICIENCIES

In addition to textual issues that are described in Section III below, the July 2012 Proposal suffers from a number of significant legal deficiencies. These issues are described below.

1. Constitutional Violations

A. Ultra Vires and Overbreadth

As a threshold matter, the July 2012 proposal is overbroad. As an illustration of this fact, the Alliance focuses the Department's attention on the plain language of the Statute. Specifically, the plain language of Health and Safety Code § 25257.1:

- (a) This article does not limit and shall not be construed to limit the department's or any other department's or agency's existing authority over hazardous materials.
- (b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.

- (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

The plain language of § 25257.1 directs the Department to develop regulations by identifying the universe of what is already regulated and drafting in such a way as to avoid any conflicts with that universe. As currently drafted, however, the July 2012 Proposal is in direct conflict with the Statute. Section 69503.2(a)(3) states:

Other Regulatory Programs. The Department shall consider the scope of other California and federal laws, and international agreements with the force of domestic law, under which the product or the Chemical(s) of Concern in the product is/are regulated, and the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product. [Emphasis added.]

Under this language, the Department would treat the existence of other regulatory programs merely as a factor to be “considered,” which falls short of the clear statutory directive to avoid duplicative or conflicting regulations. The Department appears to be attempting to reserve the right to second-guess the degree to which the regulatory programs of other agencies “provide adequate protections” with respect to any issues of concern to the Department. Taken to its logical conclusion, this language can be understood to mean that unless existing regulations address the entire lifecycle of a product to the Department’s satisfaction, the Department retains the right to regulate. This provision in the July 2012 Proposal is not consistent with the statute, nor is it faithful to the policy objectives that the legislature was seeking to achieve with § 25257.1. The goal of the legislature was to impose a clear limit on the scope of the Department’s authority. In contrast, the July 2012 Proposal would put the Department in the role of evaluating the adequacy of other agencies’ regulations and filling in the “gaps” as perceived by the Department.

In order to comply with the statute, the Department must, prior to adoption of the July 2012 Proposal, either 1) undertake a robust analysis of where conflicts exist, and amend the regulations to address the same, or 2) amend the Proposal to include an express exemption for products already regulated. Absent these changes, the July 2012 Proposal is unreasonably overbroad and subject to challenge on the grounds that it is *ultra vires*.

B. Due Process

The Summary of the Proposed Regulations (“Summary”) that was released with the July 2012 Proposal includes a Section V, which highlights the key implementation milestones for

purposes of the regulations. Notably, many of the key milestones (e.g., the First COC list², First (proposed) Priority Products list, AA Guidance, etc.) will not be released until sometime after the regulations are adopted. In addition, §§ 69505 and 69505.3(b)(2)(A)(2) of the July 2012 Proposal reference the AA Guidance and other information that is to be posted on the Department's website (but not yet available), and that must be considered in developing AA under the regulations. It is not clear when this information will be released to the public, and how this information will inform the process.

The inability to review these critical documents during the public comment period on the July 2012 Proposal raises due process concerns. Because it is virtually impossible to effectively comment on the July 2012 Proposal and preserve our rights under the APA without having access to these other key documents, the Alliance is being deprived of meaningful participation in the regulatory adoption process for the July 2012 Proposal. Moreover, various aspects of the regulatory scheme give rise to the possibility that affected entities will be deprived of property by means of a regulatory adoption process that is wholly inadequate and does not comport with the requirements of the APA. If the Department does not address these notice issues and/or the failure to comply with APA requirements, adoption of the July 2012 Proposal will most certainly give rise to valid claims for violations of affected stakeholders procedural and substantive due process rights. *Parratt v. Taylor*, 451 U.S. 527, 537 (1981) (There are two basic elements to a claim for violation of procedural due process: (1) deprivation of a protected interest, (2) by means of inadequate procedures.); *Rochin v. California*, 342 U.S. 165, 208 (1952) (Substantive due process can be summarized as a constitutional guarantee of respect for rights that are "so rooted in the traditions and conscience of our people as to be ranked as fundamental, or are implicit in the concept of ordered liberty." Where government action "shocks the conscience" or is "inherently impermissible" an action alleging a violation of substantive due process rights is proper.).

At a minimum, the Department must ensure that upon release, all documents critical to the implementation of the July 2012 Proposal are subjected to the same rigorous APA process that the July 2012 Proposal is being subjected to (see the additional discussion of notice-and-comment requirements below).

C. Vagueness/Ambiguity

Absent the ability to review the July 2012 Proposal together with the aforementioned key documents, and based upon the information that has been released to date, the Alliance must presume that one or more of the key documents referenced above will include subjective requirements that will place the validity of each said document and the July 2012 Proposal in jeopardy. Laws regulating industry must give fair notice of the conduct that is required or proscribed. This is essential to the protections provided by the Due Process Clause of the Fifth Amendment, which also requires the invalidation of impermissibly vague laws. *See FCC v. Fox*

² It is our understanding that the initial COC List has already been finalized. As a means to addressing some of the concerns set forth herein, the Auto Alliance urges the Department to release the list for consideration in connection with the July 2012 Proposal.

Television Stations, Inc. et al. 132 S.Ct. 2307, 2309 (2012), citing *Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926) and *United States v. Williams*, 553 U.S. 285, 304 (2008).

As alluded to above, the industries subject to compliance with the July 2012 Proposal are entitled to a regulatory proposal that includes objective standards that they can rely upon with certainty. To the extent that the July 2012 Proposal and/or other documents referenced in the July 2012 Proposal and released after adoption of the July 2012 Proposal do not contain reasonable, objective standards; they are all subject to legal challenge. See *People v. Mobil* (1983) 143 Cal.App.3d 261, 276, citing *Paccar, Inc. v. National Highway Traffic Safety*, 573 F.2d 632, 634 (9th Cir. 1978) (“Manufacturers who are held to standards of compliance are entitled to testing criteria that they can rely upon with certainty. The procedures should be rational and unequivocally demonstrable. Compliance should be based upon objective measures rather than subjective opinions of human beings . . . Statutes prescribing penalties, civil or criminal, must be drafted without ambiguity.”).

D. Commerce Clause

The aforementioned problems with the July 2012 Proposal implicate a fourth and final constitutional issue. As currently drafted, the July 2012 Proposal has the potential to result in unreasonable interference with interstate commerce by imposing excessive regulatory burdens on entities outside of California. As an example, product reformulation that is required under the July 2012 Proposal might ultimately impose excessive costs on manufacturers located in other states, potentially leading to job losses and other adverse economic consequences. Also, the proposal unfairly benefits manufacturers located in California who export to other states. These negative impacts may be of little concern to California, since the lost jobs would not be California jobs, but they may be a major concern in other states and regions. Moreover, the infrastructure that could ultimately be required to accomplish the Department’s preferred product reformulation may influence how and where said products are manufactured, forcing certain regulatory and land use decisions on the part of other states. In sum, the breadth (or overbreadth) of the July 2012 Proposal raises commerce clause/dormant commerce clause problems that should be further analyzed prior to adoption. This analysis should be undertaken in conjunction with the preparation of a comprehensive economic impact analysis, as discussed below.

2. APA Issues

A. Economic Impact Statement

The Economic Impact Statement prepared for the July 2012 Proposal is wholly deficient. After a cursory analysis, containing little more than general predictions unsupported by facts and analysis, the Department has concluded that: “this regulation may have a significant statewide economic impact directly affecting businesses, but that it is not expected to affect the ability of California businesses to compete with businesses in other states.” 45-Day Public Notice at 27.

Government Code § 11346.3 requires that state agencies proposing to adopt regulations assess the potential for adverse economic impacts on California businesses and individuals. Cal. Gov. Code § 11346.3(a). It requires that a state agency “consider the proposal’s impact on business, with consideration of industries affected including the ability of California businesses

to compete with businesses in other states.” *Id.* at § 11346.3(a)(2). The agency should prepare an “economic impact analysis that assesses whether and to what extent” the regulation will affect: creation or elimination of jobs in California, creation or elimination of existing businesses in California, the expansion of businesses currently doing business in California, and the benefits of the regulation to the health and welfare of Californians. *Id.* at § 11346.3(b). If, however, the agency initially determines that a regulation “will not have a significant, statewide adverse economic impact directly affecting business,” an agency does not have to prepare the economic impact analysis and “shall provide in the record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination.” *Id.* at § 11346.5(a)(8). Section 11346.3(e) provides that:

Analyses conducted pursuant to this section are intended to provide agencies and the public with tools to determine whether the regulatory proposal is an efficient and effective means of implementing the policy decisions enacted in statute or by other provisions of law in the least burdensome manner. Regulatory impact analysis shall inform the agencies and the public of the economic consequences of regulatory choices, not reassess statutory policy. . .

In *Western States Petroleum Association v. Cal. State Bd. of Equalization*, 2010 WL 3384044 (Superior Ct. L.A. County, April 27, 2010), a superior court invalidated a California State Board of Equalization (“BOE”) rule on the grounds that the economic impact statement was not sufficient to comply with Government Code § 11346.3. The court found that “[t]he Economic Impact Statement prepared by the BOE does not comply with [the § 11346.3] requirement because the calculation of costs contained therein bears no relationship to the actual effect of the change from the [old to the new methodology], and also because the BOE did not determine the cost (tax) that a [particular type of refinery] would necessarily incur in reasonable compliance with the new rule [as required under Government Code § 11346.5(a)(9)], but instead the BOE attempted to determine the cumulative economic impact of the new rule based on the aggregate assessed value of all California refineries.”

Given the fact that the Department acknowledges several potential negative economic impacts in its 45-day public notice, e.g., the regulation “may have the effect of increasing the costs of products . . . may have a possible short term minimal impact on the reduction of jobs . . . may have a significant statewide economic impact directly affecting some businesses . . .,” (*see* 45-Day Public Notice at 29-30), a more thorough analysis of potential economic impacts is required. The aforementioned conclusions, coupled with a determination that it is not possible, due to the nature of the regulations, to quantify any of the potential economic costs (businesses, jobs, and otherwise) of the July 2012 Proposal, does not satisfy the requirements of the Government Code. The Department must provide additional information about potential economic impacts, and compare said costs to those of meaningful alternatives (*See* Health and Safety Code § 57005), if it hopes to comply with Government Code § 11346.3 and avoid a successful legal challenge.

By failing to provide an economic analysis, the Department has made it impossible to assess how automakers will be affected. We are concerned that the brief review of the potential economic impacts performed by an economist for the California Foundation for Commerce and

Education indicates that the impacts on industry could be severe. The report prepared for the California Foundation for Commerce and Education by Andrew Chang and Company is Attachment E to this letter.

We urge the Department to suspend this rulemaking until it conduct a full economic analysis as required by and to consider alternative regulatory designs and language in light of that analysis.

B. Notice-and-Comment Requirements

Article 5 of the July 2012 Proposal addresses the AA process, which is at the core of the July 2012 Proposal. Within Article 5, §§ 69505.3 and 69505.4 lay out a two-stage AA process (with five steps in the first stage and three steps in the second stage), describing in general terms the purposes and goals of each step. Other portions of Article 5 address such issues as the timing and mechanics of preparing and submitting an AA report, certain factual information that must be included as part of each AA report, and the review/approval process for AA reports.

The AA process has the potential to be very time-consuming and resource-intensive, and the July 2012 Proposal leaves open a great many unknowns with respect to the process. Just to cite one example, Stage 2, Step 1 requires the responsible entity to “evaluate and compare the economic impacts of the Priority Product and the alternatives.” § 69505.4(a)(2)(C). While the proposed rules do define the term “cost impact,” they neither specify a methodology to be used in carrying out the economic analysis, nor do they provide any indication regarding what level of detail the DTSC will require. The same can be said for many of the other tasks and evaluations required by Article 5.

Section 69505(a) of the July 2012 Proposal, which is the very first section under Article 5, provides as follows:

Before finalizing the initial list of Priority Products under § 69503.4, the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article. The Department shall periodically revise and update the guidance materials.

Presumably, the guidance referred to in § 69505(a) will be used by the Department to fill in the extensive “blanks” in the AA process and give responsible parties more concrete direction on how to carry out their Article 5 tasks.

It is clear that any AA guidance the Department may issue must be subject to notice-and-comment rulemaking under the California APA, as well as future work plans and listing decisions. The APA sets forth a mandatory process in which “regulations” are subject to a notice-and-comment process before they may be formally adopted. The notice-and-comment process provides a means for the regulated community and other interested parties to communicate pertinent information to the agencies in advance of rulemaking. Among other things, this helps to ensure that the standards are feasible and take into account the realities of the affected industry.

The APA defines the term “regulation” very broadly to include “every rule, regulation, order, or standard of general application or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by any state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, except one that relates only to the internal management of the state agency.” Cal. Gov. Code § 11342(g). In other words, the applicability of the APA to a given agency communication or directive is determined by the nature of the communication or directive, not by what the agency has chosen to call it. Thus, any effort by the Department to create a “standard of general application,” to “make specific the law enforced or administered by it,” or to “govern the procedure” of such a law – even if styled by the agency as “guidance” – must be treated as a “regulation” under the APA, subject to notice and comment.

If an agency attempts to bypass the notice-and-comment requirements of the APA, the result can be an “underground regulation.” This is defined as any “regulation” that has not properly been adopted as a regulation and filed with the Secretary of State pursuant to the APA. 1 CCR § 250. Unless expressly exempted from the APA by statute, underground regulations are prohibited. *See, e.g.,* California Government Code §§ 11342.600, 11346. State agencies are prohibited from “issuing, utilizing, enforcing, or attempting to enforce” any “guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule” which is a regulation, and which has not been adopted under the APA. Cal. Gov. Code § 11340.5(a).

Here, where the DTSC is seeking to establish an all-new AA process applicable to a wide range of industries, it is especially important that the APA process be followed. Any direction the DTSC may provide to responsible entities with respect to the AA process, whether styled as “guidance” or otherwise, should be fully vetted with the public before it becomes effective. The DTSC has no more experience with the AA process than the regulated community does, and thus the DTSC needs all the feedback it can get on the processes and requirements it seeks to impose. It would not be in the best interests of the DTSC, the regulated community, or the State of California for the DTSC to release AA guidance that is unrealistic or excessively burdensome, or that would fail to achieve the desired objectives for one reason or another.

In light of the above, the Alliance hereby requests the DTSC to follow the APA notice-and-comment process for the guidance materials prepared by the DTSC pursuant to § 69505(a). In addition, since any guidance materials must go hand-in-hand with the formal regulations, it must be recognized that the publication of such guidance materials may alert the regulated community to new issues or concerns with respect to the July 2012 Proposal itself. To the extent that this occurs, the Alliance hereby requests that the DTSC accept further comments on the July 2012 Proposal at the same time that it accepts comments on the AA guidance materials.

C. Alternatives Analysis

The 45-day public notice that accompanied the release of the July 2012 Proposal includes a very brief discussion of alternatives. Among other things, the section titled: “Consideration of Alternatives” describes the purported alternatives to the July 2012 Proposal that have been considered and rejected by the Department, and clearly demonstrates that no meaningful

alternatives to the July 2012 Proposal have been given consideration over the course of the lengthy regulatory process.

Aside from the “Do Nothing” alternative, the Department claims to considered a “Products and Chemical Hazard Categories prioritization Process to Develop Safer Consumer Products,” and then goes on to describe earlier drafts of the proposed regulations as a third alternative. Prior drafts of what is now the July 2012 did not deviate substantially from the approach that is set forth in the July 2012 Proposal. Accordingly, it is apparent that the Department has done little more than summarily address one other possible regulatory approach.

Government Code § 57005 requires that before adopting any major regulation the Department “consider whether there is a less costly alternative or combination of alternatives which would be equally as effective in achieving increments of environmental protection in a manner that ensures full compliance with statutory mandates within the same amount of time as the proposed regulatory requirements.” The Alliance believes that there are several viable alternatives to the July 2012 Proposal that have yet to be considered. Attachment D to this letter identifies several alternative regulatory designs that would be equally, if not more, effective in achieving the aims of the Statute.

D. CEQA and Multimedia Environmental Review

The July 2012 Proposal has the real potential to result in “direct physical change[s] in the environment” and/or “reasonably foreseeable indirect physical change[s] in the environment,” and an initial study and programmatic environmental impact report must be completed prior to adoption of the July 2012 Proposal. See Public Resources Code § 21065 and CEQA Guidelines § 15378 (definitions of “Project”). See also CEQA Guidelines § 15168; and *Plastic Pipe and Fittings Association v. California Building Standards Commission* (2004) 124 Cal.App.4th 1390, 1413 (“Thus, an activity need not cause an immediate environmental impact to be considered a project. We conclude that the regulations here at issue may have a reasonably foreseeable indirect environmental impact for the reasons expressed [during public comment].”).

The Alliance has reviewed the draft Notice of Exemption (“NOE”) prepared to satisfy the Department’s obligations under CEQA. As indicated in previous correspondence, an NOE is not sufficient to satisfy the Department’s obligations. The NOE circulated in connection with the July 2012 Proposal does not change our opinion on this issue. Specifically, the Department’s belief that the July 2012 Proposal will “eliminate or reduce the adverse public health and environmental impacts of consumer products. . .” is simply not enough to support its reliance on a CEQA exemption. See e.g., *Dunn-Edwards Corp. v. Bay Area Air Quality Management Dist.* (1992) 9 Cal.App.4th 644,656-658 (Categorical exemption is inapplicable where adoption of regulations tightening emission standards for architectural solvents will result in environmental effects.).

CEQA analysis is required to be conducted prior to adoption of the July 2012 Proposal, and should be conducted in a programmatic EIR that analyzes the potential for impacts and potential alternatives to the July 2012 Proposal and/or specific provisions of the July 2012 Proposal that may be feasible and might reduce the potential for significant environmental

impacts in connection with its adoption. Preparation of a program environmental document will ensure that the Department considers broad policy alternatives and program wide mitigation measures at a time when the agency has the greatest ability to deal with cumulative impact problems. A programmatic document will also play an important role in establishing a structure within which future reviews and related actions can most effectively be conducted. *See In re Bay-Delta Programmatic Environmental Impact Report Coordinated Proceedings* (2008) 43 Cal. 4th 1143, 1169.

There is substantial evidence to support the conclusion that the July 2012 Proposal will cause or compel the use of alternative substances, the impacts of which are unknown and which if history is any guide, can be devastating.³ For example, the potential for environmental impacts associated with end-of-life management requirements contained in § 69506.8 of the July 2012 Proposal, and the anticipated increase in hazardous waste disposal that is likely to result from the same, must be evaluated prior to adoption of the July 2012 Proposal so that the Department can be certain that there are not feasible alternatives to § 69506.8 that would meet the objectives of the Statute and reduce the potential for environmental impacts. Finally, any perceived conflicts between the Statute and existing environmental laws that the Department believes may exempt them from CEQA and which may ultimately be the genesis of environmental impacts of their own, must also be appropriately analyzed and considered prior to adoption of the July 2012 Proposal. *See e.g., Mountain Lion Foundation et al. v. County of Kern Department of Planning and Development Services* (1997) 16 Cal.4th 105, (Delisting the Mojave ground squirrel was a discretionary action that was not properly treated as categorically exempt from CEQA. There was no irreconcilable conflict between CESA and CEQA that exempted the Fish and Game Commission's decision from CEQA's requirements and nothing in the language or history of CEQA or CESA indicated that the Legislature intended delisting to be exempt.). A more robust discussion of the requirements of CEQA and additional examples are included in Attachment F and in prior comments transmitted during the regulatory adoption process and referenced in Attachment C.

Finally, the Statute includes a separate and specific requirement that a multi-media environmental review be conducted unless it can be conclusively determined that the July 2012 Proposal will not result in environmental impacts. *See Health and Safety Code § 25252.5*. This requirement is in addition to the requirements of CEQA and is an express recognition of the potential that public health and environmental impacts are likely to result from adoption of Green Chemistry Regulations. While the California Environmental Policy Council ("CEPC") considered the multimedia environmental review issue in connection with a prior version of the regulations, neither the Department nor the CEPC have analyzed the question of whether multi-media review is required in connection with the July 2012 Proposal. The Statute is clear on this issue, and it is not appropriate to postpone that multimedia review until after the public comment period during the APA process, as it deprives stakeholders of meaningful comment on the proposed rulemaking.

3. Antitrust Issues

³ Some examples, such as methyl tertiary butyl ether ("MTBE"), are provided in the environmental analysis included in Attachment F.

There are aspects of the July 2012 Proposal that raise concerns from an antitrust standpoint. For example, the July 2012 Proposal encourages consortiums to work together in developing a single AA for an entire product line, and/or cooperate in an end-of-life management program, the anticompetitive effects of which could result in the Department selecting single source replacement for an entire industry. As a threshold matter, the Alliance notes that these two examples might compel activities that violate antitrust laws, lead to commoditization of goods, and stifle innovation that results from competitive markets.

That being said, the Alliance (and presumptively other such industry groups) are keenly aware of antitrust requirements, and cannot compromise compliance with antitrust laws. From a practical standpoint, this means that industry could be placed in a very difficult position should the July 2012 Proposal be adopted. As such, we encourage the Department to explore how it might revise the July 2012 Proposal to address these concerns and potential conflicts that may arise.

A. Barriers to Trade

As evidenced by the concerns recently raised in the Technical Barriers to Trade notification filed in August 2012 by the National Center for Standards and Certification Information (“NCSCI”) and the National Institute of Standards and Technology (“NIST”), there are concerns that the July 2012 Proposal will affect not only interstate commerce, but world trade, and potentially violate our international treaty obligations, as they may impose an illegal barrier to trade, as that term is defined by the World Trade Organization (“WTO”).⁴ The Department must consider whether there are revisions that would serve to narrow the scope of the July 2012 Proposal and that would ensure that the July 2012 Proposal is not ultimately deemed an illegal barrier to trade.

III. REGULATION TEXT

To be clear, the Alliance firmly believes automobiles should be exempted from the DTSC’s regulatory scheme. Given the extreme complexity of automobiles (as discussed previously), the plethora of existing federal and state regulations that apply to automobiles, and the scope of protections already imbedded in the decision making processes of automobile manufacturers, an exemption for our industry is warranted. This is the fundamental position of the Alliance, and it has been communicated separately to the Governor’s office. *See* Attachment G.

In addition, the Alliance also has many concerns about the July 2012 Proposal, some of which have already been enumerated in our prior comments. In Attachment A, we provide suggested language to help address five major concerns (discussed in Section I., above). We strongly urge the Department to incorporate these revisions in the regulations. It should be noted that this list is not all encompassing, but rather their inclusion will form a meaningful basis for the further discussions and changes necessary to create a workable program. To assist the

⁴ We incorporate by reference the concerns raised in the letter submitted by Mr. Guiseppe Casella of the European Union regarding the potential for unequal treatment of economic operators.

Department in this endeavor, we have provided a redline of the entire text in Attachment B which address only these five concerns and not all of our concerns with the Proposal. Additional concerns are listed below in order of appearance in the text.

1. **Article 1. General.**

A. **Purpose and Applicability**

As currently drafted, the language in this section is so broad that it could be read to include the regulation of tailpipe emissions. This is simply not the intent of the Statute, and tailpipe emissions are already regulated subject to a national program for vehicle greenhouse gas (“GHG”) emissions and fuel economy, as well as the criteria pollutant emission regulations already in place in California. Nevertheless, the following statement on p. 22 of the Initial Statement of Reasons (“ISOR”) signals the Department’s view that these regulations could play a role in the regulation of GHG emissions from vehicles: “For example, DTSC could identify the catalytic converter in a vehicle as the component that must undergo an AA due to the release of nitrous oxide, a potent greenhouse gas.”

This telling statement raises major concerns for a variety of reasons. First, the California legislature has delegated the regulation of motor vehicle emissions, including GHG emissions, to the California Air Resources Board. *See* Health and Safety Code § 43000 *et seq.* There is no reason for the DTSC to enter this field. Second, the State of California has recently made a commitment to President Obama and the U.S. Environmental Protection Agency (“EPA”) to support the so-called “One National Program,” which enables automobile manufacturers to comply one set of with federal GHG standards rather than state-by-state GHG regulations. The Department’s proposal undermines One National Program barely one model year into that program’s existence by suggesting that the DTSC, rather than the California Air Resources Board (“CARB”), can impose additional state-based GHG-related requirements on automakers.

Third, and as discussed previously, the Statute specifically prohibits the Department from regulating products where to do so would raise a conflict, or be duplicative of existing regulatory requirements. *See* Health and Safety Code § 25257.1 (“ . . . This article does not authorize the department to supersede the regulatory authority of any other department or agency. The department shall not duplicate or adopt conflicting regulations. . .”). Instead of complying with this Directive, the Department’s own ISOR posits this example of how the July 2012 Proposal can be used to impose new requirements that overlap and interfere with the regulatory authority of another agency.

A further troubling aspect of the catalytic converter example is that the basis of the DTSC’s “jurisdiction” for addressing the product is not the harmful properties of a chemical of concern contained within the product; instead, a release from the product is considered the COC. Priority products should be selected based on the COC in the product, which is the intent of the enabling statute:

On or before January 1, 2011, the department shall adopt regulations pursuant to this section that establish a process for evaluating chemicals of

concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.” § 25253(a)(1) [emphasis added].

Furthermore, catalytic converters by themselves do not release GHGs; automobiles do, and catalytic converters are but one element of a much larger system. Any analysis of GHG emissions from motor vehicles necessarily encompasses a host of components, including fuels, potentially opening the door for an attempt to re-engineer large portions of the vehicle under the guise of green chemistry. For all of these reasons, the scope of the July 2012 Proposal is unworkable.

B. Definitions

The July 2012 Proposal expands the applicability of the regulation into areas not contemplated by the statute as is enumerated below.

“Adverse air quality impacts” – The current definition of adverse air quality impacts is so broad that it exceeds the scope of DTSC’s authority under the Statute. The definition must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and AA process, and so that the process for selecting Priority Products is appropriately transparent.

As the starting point for establishing quantitative thresholds, the Alliance suggests a review of thresholds applicable in the California Environmental Quality Act CEQA context. Notably, Public Resources Code § 21151.4(a) provides:

An environmental impact report shall not be certified or a negative declaration shall not be approved for any project involving the construction or alteration of a facility within one fourth of a mile of a school that might reasonably be anticipated to emit hazardous air emissions, or that would handle an extremely hazardous substances in a quantity equal to or greater than the state threshold quantity specified pursuant to subdivision (j) of Section 25532 of the Health and Safety Code... [Emphasis added].

Health and Safety Code § 25532(j) references 40 CFR 355, Appendix A, which includes a list of hazardous substances and the quantity intended to be regulated. Similarly, Health and Safety Code § 21151.4(a)(2) defines “hazardous air emissions,” and Health and Safety Code § 44321 clarifies what specific substances and quantities are intended to be regulated. Any project proponent should be able to effectively assess whether their project has the potential to exceed applicable thresholds by reviewing the aforementioned provisions so that, in an instance where there is the potential for triggering the same, they can make project changes meant to address potential exceedances prior to undertaking the environmental review process. In other words, by establishing transparent, quantifiable thresholds, the legislature has built-in the means, and an incentive to designing a project that complies with applicable standards. Moreover, this can be done in advance of subjecting any project to the formal regulatory process.

By way of example, Appendix G to the CEQA Guidelines provides direction on the means to establishing quantitative thresholds that would be appropriate in the green chemistry context. For example, pursuant to Appendix G, Section III., item (b), a project that violates stationary source air quality standards or contributes to existing or projected air quality violations will be determined to have a potentially significant air quality impact under CEQA. The means to determining whether the aforementioned violations will occur is quantifying baseline emissions in the project vicinity and comparing the baseline + project emissions to ambient air quality standards. No doubt, there are quantitative standards applicable to emissions of nitrogen oxides, particulate matter, sulfur oxides and other criteria pollutants intended to be covered by the definition of "adverse air quality impacts." In the event baseline + project emissions exceed those quantitative standards, a potentially significant impact conclusion is reached unless: (1) the project is modified to eliminate the exceedance; or (2) mitigation intended to address the exceedance is imposed. In the GHG context, rules, regulations and guidance like EPA's tailoring rule, South Coast Air Quality Management District's ("SCAQMD") Interim Guidance and Delaware and New York regulations applicable to hydrocarbon emissions, provide clarity about the levels of GHG emissions that implicate a potentially significant impact. Again, the existence of transparent, quantifiable thresholds gives project proponents a clear understanding of what constitutes a significant or adverse impact, and encourages design that will minimize or eliminate the same.

In order to remain consistent with the goals of the Statute, to ensure that the regulations are not overbroad, and as a means to encouraging forward thinking and innovative design, this definition must be revised to reference or incorporate quantitative guidelines for determining what an "adverse air quality impact" is.

"Adverse ecological impacts"/"Adverse public health impact"/"Physical chemical hazards"/"Physicochemical properties" – The Alliance is concerned that the OEHHA regulations that are also being adopted as part of the larger Green Chemistry Initiative, and that are referenced in these definitions, are too broad. In addition to the due process concerns raised by references to definitions from another potential rulemaking, the definitions lack a scientific basis, and exceed the grant of authority provided by the Statute. The Alliance urges the Department to coordinate with OEHHA on these issues, and to provide an opportunity for the public to comment on both sets of draft regulations in the same rulemaking process. This will ensure that definitions and standards are consistent and work in concert with the Statute's prioritization mandate.

"Adverse waste and end-of-life impacts" – As currently drafted, this definition dictates that any stewardship plan adopted to address end-of-life impacts would be required to address not only the COCs that were the drivers for listing any Priority Product, but also for "Any other chemical contained in the alternatives that differs from the chemicals contained in the Priority Product." In other words, it requires that any stewardship plan address the whole product, regardless of what chemical or component was selected for AA. This is troubling, and signifies that the manufacturers of Priority Products may ultimately be subject to end-of-life management requirements that have no rational connection to the chemicals or components that are the subject of this regulatory process. This definition is overbroad. The intent of the Statute is regulations

that focus on the COCs in certain designated components of any Priority Product, and this definition should be revised accordingly.

“Alternative” – The Alliance is also concerned about the breadth of this definition. The current version is written broadly enough that regulatory responses could apply to actions that only involved removal of any COC (without any other changes) in a Priority Product. From an efficiency standpoint, this makes little sense. Where a COC is removed, and no other changes are made, there is little or no likelihood of outcomes including “regrettable substitutions.” Accordingly, subsection (A) should be removed from this definition.

Again, in order for the Department to implement the July 2012 Proposal efficiently the regulations and their requirements must be streamlined to the extent possible.

“Component” – The current definition of component is also too broad. As currently drafted, it could still be read to include multi-component systems that are contained within a “highly durable product” like an automobile (e.g., engines, transmissions and fuel systems). Consistent with the concerns that were raised when the regulations did not distinguish between homogenous and assembled products, the Alliance is concerned that a definition this broad will complicate compliance for the auto industry, and for the manufacturers of other “highly durable products.” For a durable consumer product (such as an automobile), longer product cycles and product development times is required partially to ensure durability requirements are met. When the definition of components includes assemblies and systems which contain numerous components and the potential for hundreds of parts (such as in an engine or transmission), even longer testing and development time is required due to the complexity of the system. Moreover the proposed definition of “component” is not in keeping with the Department’s repeated statements regarding its intent to regulate materials in components and the accompanying examples given (adhesives used in carpets, a flame retardant in foam, etc.). Additionally, it is hard to see how such an approach would be effective at addressing a COC release to the environment when targeted actions are both more efficient and effective (as is the case in elimination of lead use in wheel weights and recent actions to address copper in brake pads). As such, we continue to believe that revisions to this definition are necessary.

“Consumer product/product” – While this definition appears to exempt certain “historic products,” or “a product that ceased to be manufactured prior to the date the product is listed as a Priority Product,” it does not go far enough. The Statute, specifically Health and Safety Code § 25253(b) makes it clear that the legislature did not intend to regulate certain products that were manufactured prior to development of a Priority Products list. While the Priority Product listing comes before the analysis, from a practical perspective, the legislature could not have intended to regulate assembled products like automobiles (which require a significant investment, and that are intended to remain viable long after their manufacture) in a manner that would require *de facto* replacement anytime an individual component becomes subject to a regulatory response that might require the same. From a practical standpoint, the term “historic product” must include service and repair component(s) for any automobile that is manufactured or produced prior to the date the component(s) are listed as a Priority Product. A broader definition of “historic products” must be incorporated into the July 2012 Proposal.

“Reliable information”/“Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical” are overly broad and not based on solid scientific principles. As a threshold matter, it is not clear why two separate definitions are required here. Accordingly, we suggest that they be consolidated, and that one definition for “Scientifically reliable information” replace § 69501.1 (52) and (53) in the July 2012 Proposal. This definition must exclude “other literature” as that is overbroad. This definition must also exclude individual published peer-reviewed studies that do not meet the OECD quality and reliability standards. Only studies confirmed by a recognized and established scientific body should be included in the definition of “reliable information.” Without these changes, DTSC risks undermining its entire program.

Notwithstanding the above, as currently drafted, both §§ 69501.1(52) and (53) are arbitrary, and not based on science. There is no clear indication about why studies “conducted, developed, submitted or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes” would constitute “reliable information” vis-à-vis others. Moreover, the categories listed in (52)(A)-(D) are not tied to objective standards that manufactures can rely upon. Again, presence does not dictate exposure. Accordingly, (A)-(D) should include or reference quantifiable standards for determining whether an occurrence, potential occurrence or exposure to a chemical can be demonstrated.

As an alternative to the language currently contained in § 69501.1(52), the Alliance offers some suggested edits in the attached redline, and also supports the definition proposed by the Green Chemistry Alliance (“GCA”) in prior comments:

Reliable information’ is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship (“QSAR”) approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies.

In order to address Alliance concerns about § 69501.1(52), we suggest tying (A)-(D) to reportable quantities.

C. Information Submission and Retention Requirements

The July 2012 Proposal continues to include a requirement that most relevant submissions be signed and certified under oath by the owner or officer of the company or their authorized representative and by the individual responsible for preparing or overseeing the preparation of the documentation or information. Only the person preparing the relevant document should need to verify the accuracy of the document they prepared. It is not necessary

for senior management to review every notification sent to the Department, particularly the proliferation of notifications that this proposed regulation contemplates. The requirement for owner and operator involvement and to require two sets of signatures is over-reaching and impractical. It creates an administrative burden that will not further the accuracy of the documents filed with the Department, since the person with most knowledge is already required to sign. Moreover, it is not necessary to effectuate the Statute.

D. Chemical and Product Information

Per statements by the Department, the intent of these provisions is only to touch information generated in connection with Priority Products, and is not to require the generation of new information and paper by responsible entities prior to initiation of the AA process. As currently drafted, subsection (a) is much broader than this stated intent. First, subsections (a)(3) and (a)(4) permit the Department to request a “responsible entity” to make available/generate information without specifying when this power might be invoked. In addition, the definition of “responsible entity” should be limited to manufacturers, importers and retailers of “Priority Products,” rather than manufacturers, importers and retailers of any “consumer product.” Finally, if the Department’s intent is as it suggests, it should not be necessary to generate new information in response to any request. Therefore, subsection (4) is unnecessary. The language in subsection (a) must be revised for consistency with the Department’s stated goals, and the Statute.

2. Article 2. Chemicals of Concern and Consumer Product Prioritization Process.

A. COC Identification

The July 2012 Proposal lacks needed scientific prioritization principles and provisions. The COC list should ultimately reflect serious thinking and study on the potential harms and exposures from chemicals listed. The process here is too loose and overbroad. It allows the Department to add to the COC List at any time based on “reliable information,” the current definition of which raises the concerns discussed above. The result is that 1,200 or more chemicals will be on the list (which can be expanded at will), when the list can and should be further refined in order to facilitate efficiency in implementation of the regulations, and must be refined if the regulations are to maintain consistency with the Statute. *See* Health and Safety Code § 25252 (“On or before January 1, 2011, the department shall adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern...” [emphasis added]). *See also Hunter v. City of Whittier* (1989) 209 Cal.App.3d 588 (Ordinance too broad to satisfy the purpose of implementing authority unless standards were objective and reasonably defined.).

In order for the Department to truly send signals to the marketplace on what chemicals present the greatest concern, and to stimulate the immediate cooperation of industry to find safer substitutes, the COC list must be carefully and thoughtfully developed and prioritized. As this draft currently contemplates, the initial list will be over 1,000 chemicals and the signal to the

marketplace is dispersed and unknown. The reaction of industry will likely be to wait and see what priority products are selected.

Given that the Department has not actually published the list of chemicals, but rather provided a vague list of lists, it cannot even be known what the possible impacts are to product manufacturers. If the list will not be made available during the comment period for this rulemaking, then the future process for listing COCs must comply with the APA. The Department must provide a notice and comment period prior to identification and finalization of the COC list. This will allow interested parties to submit valuable information that may not currently be available to the Department that will better inform its ultimate COC listing determinations.

A step-wise approach to the identification of COCs would serve the Department's goals without increasing the regulated community's burden, and would render the prioritization process more transparent and fair. Absent revisions of this nature, this section is overbroad and does not reflect the intent of the Statute, nor will it be effective. A list of 1,200 COCs is an order of magnitude too large to implement effective reductions of listed chemicals, reflecting a lack of effective prioritization. The Alliance urges the Department to consider how it might revise this section for improvement in that regard.

3. Article 3. Chemicals of Concern and Consumer Product Prioritization Process.

A. Priority Products Prioritization Factors

Generally, § 69503.2 is improved as it is much more focused on exposures, potential exposures, and pathways for exposure. This will appropriately limit the universe of products to those with the greatest potential to harm the public and the environment, and is consistent with the goals of the Statute.

However, rather than actually setting forth the methodology the Department will utilize to prioritize products, the July 2012 Proposal merely identifies a number of factors the Department's staff will consider. The actual prioritization then undergoes a 180-day decision making process that lacks clear criteria. This will discourage manufacturers from seeking to get ahead of these regulations and accelerate their design of green safer products or their choice of greener, safer chemical ingredients. We urge the Department to completely re-craft this process, and to instead design a process that engages in triage and prioritization based on sound scientific principles, using a robust peer and public review.

In addition, § 69503.2 violates the statutory requirement for an exemption where there would be a conflict with, or duplication of existing laws and regulations. This should not be a judgment call of DTSC; the existence of other laws that conflict with or duplicate should, in itself, be sufficient to exempt those products. Thus, it is necessary that revisions address this inconsistency between the Statute and the July 2012 Proposal.

B. Priority Products List

Section 69503.4(a)(2)(B)(2) of the July 2012 Proposal provides that for each “highly durable product” the Department shall specify no more than ten components and/or homogenous materials per product every three years. Given the enormity of the Department’s undertaking, and the complexity of highly durable products, the Alliance is concerned that this schedule is much too aggressive for both the Department and industry. The Alliance suggests that a change to no more than five components per product every three years is still an aggressive undertaking, but one that may be achievable. Additionally, without changing the definition of components as we have suggested, the limit of even five components being addressed every three years is impractical, particularly if the components include complex assemblies such as engines and transmissions.

Section 69503.4(f) provides that the Department shall review and revise the Priority Products list at least once every three years. This implies that the Department could make changes at intervals shorter than three years. Consistent with the above, this provision is simply too aggressive and should be revised accordingly.

C. AA Threshold Exemption

The Alliance supports the Department’s decision to abandon the term *de minimis* threshold, and instead utilize “Alternatives Analysis Threshold.” Moreover, it appreciates the fact that § 69503.5(c) gives the Department flexibility in specifying the threshold for each COC that is the basis for a product or component being listed as a Priority Product. That said, in order for the implications of the threshold to be clearly understood and practically implemented, we recommend that the reliable information standard be further clarified in this section of the July 2012 Proposal. Specifically, the Alliance recommends that the following definition be added and referenced in § 69503.5:

Practical Quantitation Limit (PQL)” means the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the chemicals of concern in the listed priority product results in an exemption for that product from the alternatives assessment process.

Alternative Analysis thresholds should then be set at or above the PQL.

In addition, and in an effort to streamline the regulatory process by focusing on an achievable scope of chemicals, we recommend that § 69503.5(c)(1) be revised to exempt naturally occurring contaminants and recycled material contaminants from consideration. Attempting to regulate trace levels of naturally occurring contaminants is impractical and counterproductive to controlling, reducing or eliminating intentionally added COCs. Addressing contaminants in recycled materials will surely inhibit the use of recycled content in products, which cannot be the Department’s intent.

The focus of the Green Chemistry Statute is on design of safer consumer products and design of safer green chemistries and materials. By not exempting contaminants, the Department

is redirecting the energies and monies of industry from the important goals of the statute to lower value environmental goals.

D. AA Threshold Exemption Notifications

Section 69503.5 should be struck from the regulation. If a product contains a COC which is below the alternative assessment threshold, notification to the Department of such should not be required. The point of the threshold is to specify a level above which action should be required and, conversely, below which no action is required. An exemption notification requirement will detract resources from the task at hand – reducing COCs – and is also counterproductive. Trying to account for trace levels of chemicals, which are acknowledged by the Department as not being a priority because they are below the AA threshold set by the Department, serves no purpose and will create a burden for responsible companies. Companies (such as Alliance members) which are actively managing chemicals in their products will face a massive paperwork exercise. Companies which are not managing the chemicals in their products will simply not submit notifications. (If they do not know the chemical content of their products they will certainly not know the trace amount of chemicals which are presumably not intentionally added.) Again, with this provision, the Department is redirecting the energies and monies of industry from the important goals of the statute to administrative paperwork tasks.

As an illustration of the inefficiency likely to be associated with the AA Exemption Notification requirement, see subsection (c) which requires that AA Exemption Notification continue to be revisited and refined over the life of any product. Again, self-policing under the threat of enforcement seems more practical, and would eliminate a significant administrative burden.

4. Article 4. Petition for Inclusion of a Chemical or Product in the Identification and Prioritization Processes.

The Alliance remains concerned that this Article still contains no requirement that the Department include affected manufacturers and importers in the petition process. In order to comport with due process requirements, the provisions in this article, and specifically §69504, should be revised to provide for affected manufacturer/importer participation as early as possible, and should include a scientific peer review process.

A. Applicability and Petition Contents

Consistent with prior comments about the need for the definition of “reliable information” to be based on sound scientific principles, petitions to the Department to add COCs to the COC list must be based on sound scientific data, and the rigor of a science-based prioritization review subject to full due process rights of the APA. The regulations must include scientifically-established thresholds and standards that must be met in order for a petition to be granted.

5. Article 5. AA.

A. AA: General Provisions

While § 69505.1(a)(1) recognizes that the term “Priority Product” may mean a listed product, or the component(s) and/or homogeneous materials(s) within a component in the product that are the focus of the AA, it does not appear that the remainder § 69505.1, and many other provisions in the July 2012 Proposal acknowledge these critical distinctions. As an example, the Alliance directs the Department's attention to § 69505.1(a)(2) in the July 2012 Proposal which provides: “All references in this article to ‘product’ mean the product as a whole.”

From a practical standpoint, the language in subsection (a)(2) dictates that the entirety of a “highly durable product” will ultimately become the focus of an AA even though the Department has repeatedly stated its position that this is not its intent. To prevent this outcome, the Alliance urges the Department to make the revisions in § 69505.1 and in other provisions of the July 2012 Proposal that are necessary to ensure that, where applicable, component(s) and/or homogeneous material(s) in components, rather than a larger product, are the focus of an AA.

The language contained at § 69505.1(g)(1)(F) is simply impractical. First, like the AA Threshold exemption, the COC Removal Notice is wholly unnecessary. Nonetheless, once a COC has been removed, a product reformulated, and a COC Removal Notice submitted, requiring that the responsible entity also track all existing inventory and ensure that products still containing that COC not be placed into the stream of commerce in California, while also meeting its existing regulatory burdens and complying with all other aspects of the July 2012 Proposal is simply impractical. As the Department has acknowledged repeatedly, the regulations are intended to be forward looking, and this provision is inconsistent with that intention. The Alliance suggests that this provision be deleted. At the very least, responsible entities must be given longer than 180-days to satisfy this requirement.

B. AA: First Stage

While subsection (b)(3) allows the responsible entity to eliminate alternatives during this initial screening phase, it does not allow eliminating alternatives based upon economic, consumer acceptance or performance considerations. These are important factors in choosing an alternative that is actually implementable. Additionally, subsection (b)(3)(A) is overly broad and would require a review of chemicals not on the COC lists. Suggested revisions to address these issues is in the attached redline.

C. Alternatives Analysis Reports

The provisions of § 69505.5 are simply too broad. The massive amount of information that the Department proposes be collected will render implementation of the regulations burdensome for the both Department and industry. Moreover, a regulatory framework with more reasonable parameters would satisfy the intent of the Statute. As an example of where § 69505.5 could be revised, the requirement that responsible entities provide the name and contact information for all parties who purchased products within the last 12 months is wholly unnecessary, and a task that will require hours of manpower in and of itself. Moreover, it is confidential business information that cannot be disclosed. Again, if the goal of the July 2012

Proposal is to be forward looking, generating this type of information simply should not be a priority.

6. Article 6. Regulatory Responses.

A. AA Report Supplemental Information Requirements

This section provides that the Department “may at any time” require the responsible entity to “provide any information” and/or “obtain or develop information to fill one or more of the information gaps...” The Department has indicated that its intent is not to require the generation of information in order to fill data gaps. This provision appears overly broad and contrary to that stated intent. Accordingly, the Alliance requests that the Department revise this section for consistency with prior statements of intent.

B. Product Information for Consumers

Section 69506.4 suffers from the same problems discussed with references to § 69501.1(a)(1), above. It requires that information be provided for the whole of a product, as opposed to the component(s) and/or homogeneous material(s) within a component in the product that are the focus of the regulation. Therefore, it also must be revised to reflect what the Department has stated is its intent.

Subsection (a)(1)(D) provides that the information made available to consumers include identification of any end-of-life management program and be available for as long as the product is in the stream of commerce. To the extent there is a disagreement about inclusion of the end-of-life management requirement, this provision is also objectionable and should be revised. See below for further discussion.

C. Use Restrictions on Chemical(s) of Concern and Consumer Products

The provisions in § 69506.5 which would allow the Department to restrict who may purchase or use a product go beyond the authority conveyed in the Statute and are wholly unnecessary to effectuate its intent. Accordingly, we suggest that § 69506.5(a) through (d) be deleted in its entirety.

D. End-of-Life Management Requirement

This section requires manufacturers to develop, fund and manage an end-of-life stewardship program for their products that generate hazardous waste. This provision is unnecessary. The statute does not authorize imposition of financial guarantees or compensation to retailers, local governments and others. Also, it is pre-empted by the federal Resource Conservation and Recovery Act (“RCRA”) insofar as it conflicts with many of RCRA’s provisions, and RCRA occupies the field where these issues of end-of-life for hazardous waste management are concerned. RCRA already requires financial guarantees for end-of-life management of hazardous waste. Moreover, RCRA requires all owners and operators of facilities that treat, store, or dispose of hazardous waste to provide financial assurance.

It may also be in conflict with the Electronic Waste Recycling Act and associated regulations promulgated by the Department. Moreover, it is excessively punitive in light of the fact that manufactures already paying an advanced disposal fee in connection with the Electronic Waste Recycling Act will now potentially be asked to provide an additional up-front guarantee of environmental practices that occur at the back end of their product's life-cycle. For these reasons, the requirements (most notably the financial guarantee aspect of the requirements) are not legally defensible and this provision must be revised.

Finally, subsection (d) provides that a responsible entity may request an exemption from the requirement to provide an end-of-life management program. Once again, however, the subsection provides no standards or clear criteria for obtaining the same. This provides industry no direction with respect to what might be considered compelling, and breeds a system where there are no clear arguments in the event of an arbitrary decision.

For each of the reasons set forth above, this section requires extensive revisions. The Department should delete the end-of-life management requirement and/or build flexibility into the existing provisions that would allow for opt-out by individual companies or industries (like the auto industry) that can demonstrate (by meeting quantitative standards) that a recycling system is in place or that they have voluntarily implemented their own effective take-back or recycling programs. Provisions of this nature would provide an incentive to manufacturers developing innovative end-of-life strategies on their own, and would minimize the Department's burden in a time of scarce resources and economic uncertainty. At a minimum, the need for the financial guarantee provisions contained at § 69506.8(a)(2)(A) should be revisited.

E. Regulatory Response Selection and Re-Evaluation

While the Alliance understands that the Statute conveys authority that allows the Department to impose one or more regulatory responses, it is concerned about the implications of the language contained at § 69506.10(b). From a practical standpoint, certainty is of relevance. As currently drafted, this provision could mean that a responsible entity invests significant capital in undertaking a regulatory response imposed by the Department, only to be told that the Department has changed its mind, and would instead like to impose a different regulatory response. The threat of this sort of outcome is certain to have a chilling effect on business and innovation in California. Moreover, it is not necessary to effectuate the intent of the Statute. Accordingly, we suggest that subsection (b) be deleted in its entirety.

Additionally, there should be a point where the responsible agency is deemed to have complied with its obligations under the rules and the process is concluded, as opposed to a never-ending re-evaluation of the chemical and product combination. If new evidence of a concern appears, the product and chemical combination should once again go through a meaningful product prioritization process. The Department must add a "no further action" provision to the draft regulations.

F. Exemption from Regulatory Response Requirements

Subsection (b)(6) provides that if a responsible entity claims exemption from regulatory response requirements because to require the same would conflict with, or be duplicative of,

other applicable state or federal laws, they submit a formal request for exemption from the Department. The Statute specifically precludes the Department from requiring a regulatory response where either of these two scenarios occurs. Accordingly, no notification should be required, nor does requiring one appear to be authorized by the statute. This requirement should be deleted.

7. Article 10. Trade Secret Protection.

This Article addresses trade secret protection. While the existing provisions are not objectionable, the Article would be more appropriately protective if it covered a broader category of information and set forth how the Department intends to ensure that trade secrets are actually protected.

As a means to being appropriately protective this Article should address “Confidential Business Information,” which includes not only trade secrets, but also commercial or financial information that is privileged or confidential, including customer lists. Moreover, it must set forth a protocol that contains information security systems, employee protocols and training to assure that the Department has the ability to protect trade secret information that is supplied in connection with the July 2012 Proposal. To our knowledge, the Department does not have such a protocol in place, and without it, there is no means to actually ensuring that trade secret information is actually protected, even if it is the Department’s intent to do so.

A. Assertion of a Claim of Trade Secret Protection

Notwithstanding the above, the amount of information that must be provided to assert trade secret protection appears more cumbersome than necessary. As an example, see federal regulations at 49 CFR Part 512, which provide for protection of the broader category of “Confidential Business Information” and require far less information to support a claim.

8. Other Issues

Finally, the Alliance is also concerned that the ISOR does not provide any justification to support the adoption of language discussed in detail above. *See* California Government Code § 11346.2(b) (Requires that the ISOR include: (1) A description of reasonable alternatives including the reasons for rejecting said alternatives and a description of alternatives that would lessen any adverse impacts; (2) “efforts, in connection with a proposed rulemaking action, to avoid unnecessary duplication or conflicts with federal regulations contained in the Code of Federal Regulations addressing the same issues;” and (3) “A statement of the specific purpose of each adoption, amendment, or repeal, the problem the agency intends to address, and the rationale for the determination by the agency that each adoption, amendment, or repeal is reasonably necessary to carry out the purpose and address the problem for which it is proposed. . .”).

A. Alternatives

Consistent with the AA comments set forth in Section II., above, the Alliance also wishes to point out that the AA prepared in connection with the July 2012 Proposal is also in conflict

with the Office of Administrative Law (“OAL”) process set forth in Government Code § 11346.2(b) for two reasons:

1. The ISOR does not include a description of reasonable alternatives, and reasons for rejecting said alternatives.
2. The ISOR does not include a description of reasonable alternatives to the regulation that would lessen any adverse impact on small business, and the Department’s reasons for rejecting the same.

Again, the Department has done little more than briefly consider and summarily address one additional regulatory approach, which, given the importance of these regulations and the potential impacts to affected parties, cannot possibly constitute an analysis of “reasonable alternatives.” In addition, however, and also discussed in Section II., above, there is no doubt that the July 2012 Proposal will have economic impacts on all businesses (including small businesses). The ISOR does not include an analysis of any alternatives that would lessen adverse impacts on small business and the Department’s reasons for rejecting said alternatives.

B. Unnecessary Duplication/Conflicts

The ISOR contains a cursory analysis of why the July 2012 Proposal does not conflict with the federal Toxic Substances Control Act of 1976 (“TSCA”) and, therefore, does not duplicate or conflict with existing federal law. While this may be the case with respect to TSCA, the breadth of the July 2012 Proposal dictates that it most certainly conflicts with other federal regulatory schemes that address the environment. s the Ultra Vires and Overbreadth discussion in Section I., above. Moreover, as discussed in several places above, the July 2012 Proposal’s provisions on Trade Secret Protections are far more onerous than existing federal requirements, and the Department has failed to provide any reasonable explanation for why that is the case.

C. Statements of Specific Purpose and Rationale

The statements of specific purpose for each provision in the July 2012 Proposal do not meet the standard set forth in the Government Code. In many places, the ISOR simply repeats the language contained in the July 2012 proposal, rather than explaining the purpose of the same, problem intended to be addressed, etc. As examples, the Alliance would direct the Department’s attention to the ISOR language on: Chemical and Product Information; COC Identification; and Trade Secret Protection.

The statement of specific purpose developed in connection with § 69501.4(a) of the July 2012 Proposal does not meet the standard set forth in Government Code § 11346.2(b). It does little more than repeat the regulatory language. Moreover, despite repeated comments and repeated Department statements about the intent of the product information provisions, it contains no explanation for why subsection (4), which would allow the Department to request that responsible entities or chemical manufacturers generate new information and provide said information to the Department (irrespective of whether their chemical or product is contained on the initial COC or Priority Product lists), is necessary to carry out the purpose of the Statute.

Despite repeated comments explaining why the COC identification process that is set forth in the proposed regulations must comply with the plain language of Health and Safety Code § 25252 and “prioritize” chemicals that are found in consumer products, the July 2012 Proposal still sets forth a regulatory scheme whereby as many as 1,200 chemicals will be contained in the initial COC list. The ISOR itself acknowledges that the initial COC list is “robust,” and suggests the Department’s understanding that what will be accomplished pursuant to § 69502.2 in the July 2012 Proposal is something less than the prioritization that the legislature envisioned when it adopted the Statute. *See* ISOR at pp. 56-57. Furthermore, the ISOR does not include the rationale for the Department’s determination that a regulatory scheme that does not better “prioritize” is necessary to carry out the purpose and address the problem for which it is proposed. Without this explanation, one has no choice but to assume that there is a means to better “prioritizing” COCs and developing a more manageable initial list of COCs, a list that would better reflect the intent of the Statute and more appropriately carry out its purpose. The mere fact that longer lists guide alternative regulatory schemes is not enough to justify the Department’s approach where further prioritization is both reasonable and feasible.

As discussed above, the July 2012 Proposal provisions relating to trade secrets and trade secret protections are unnecessarily burdensome and wholly inadequate to ensure the protection of valuable trade secrets. Aside from summarizing the requirements of Article 10 in the July 2012 Proposal, the ISOR does little to explain why such a narrow scope of protection is reasonable and why such a burdensome process for asserting trade secret protection is necessary to carry out the purposes of the Statute. Where a parallel scheme exists under applicable federal regulations, and such critical information is at stake, the Government Code requires a better explanation for why broader protection of trade secrets is not enough to carry out the purpose of the Statute and to address the issues that gave rise to the Green Chemistry Initiative.

While the Alliance has chosen only to highlight these specific examples, similar deficiencies exist with respect to multiple ISOR statements. The Alliance urges the Department to revisit the statements of specific purpose for every provision of the July 2012 Proposal with an eye toward ensuring that the plain language of Government Code § 11346.2(b)(1) is satisfied with respect to each.

IV. CONCLUSION

The Alliance will continue to communicate with the Department in hopes of obtaining a practical and meaningful regulation which implements the principles of green chemistry. To that end, we have supplied numerous attachments to this letter that we hope will serve as a guide to the Department as it embarks on its next draft.

As always, thank you for your time and consideration of our comments. If you have any questions, please feel free to contact me.

Ms. Jones, DTSC
October 11, 2012
Page 30

Sincerely,



Filipa Rio
Senior Manager, Environmental Affairs,

Attachments: Attachment A: Top 5 Issues: Critically Necessary Text Revisions
Attachment B: Complete Text Redline to Make Practical, Ensure Compliance is Feasible and Improve Workability of Regulations
Attachment C: Index of Alliance Comments (with CD-Rom)
Attachment D: APA Regulatory Alternatives
Attachment E: Economic Analysis
Attachment F: Environmental Impacts Analysis (with CD-Rom)
Attachment G: Letter to Governor Brown

ATTACHMENT A: TOP FIVE CHANGES NEEDED

Top 5 Issues	Suggested Language Revisions to July 27, 2012 Draft
One	Set achievable project scope
	<p>69503.4 .1 (a)(2)(B)(4) Subparagraph 2. does not apply to either of the following types of products: For purposes of subparagraph 2, “component” means a uniquely identifiable material within a single uniquely identifiable part or piece, not comprised of subparts, of a highly durable product.</p> <p>§ 69503.4(a)(2) For each listed highly durable product, the Department shall specify no more than ten (10) <u>five (5)</u> components and/or homogenous materials per product every three (3) years.</p> <p>§ 69501.1 (34) <u>“Historic product” means a product manufactured prior to the effective date of the regulatory response selected by the Department for the Priority Product, including all service, repair and replacement parts associated with the historic product even if manufactured after a regulatory response.</u></p> <p>69501.1 (22)(B)(1) “Consumer Product” or “Product” does not mean historic product.</p> <p><u>§ 69506 (d) In no case shall the Department apply a regulatory response to a historic product. In the case of service, repair and replacement parts for historic products, the Department may only impose regulatory responses related to handling and warning requirements.</u></p>
Two	Set achievable chemical scope
	<p>§ 69501.1 <i>Add definition</i> <u>(48) Practical Quantitation Limit (PQL)” means the minimum concentration of a chemical that can be precisely quantified (percent relative standard deviation within +/- 10%) with an acceptable bias (percent recovery within 90-110%). An analytical result below the PQL obtained from an accepted analytical test method for the chemicals of concern in the listed priority product results in an exemption for that product from the alternatives assessment process.</u></p> <p>§ 69503.5. (c) The Department shall specify an alternatives analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product. In establishing an alternatives analysis threshold, the Department shall <u>exempt for a highly durable product:</u></p> <ul style="list-style-type: none"> (1) <u>A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product; and</u> (2) <u>A contaminant in recycled materials that are common and are frequently used to manufacture the product. ;</u> <p><u>and, except as provided in paragraph (3), take into consideration, based on available reliable information, the factors specified in paragraph (1), if relevant, and paragraph (2):</u></p> <p>(1) The ease or difficulty of removing from the product, or otherwise avoiding the presence in the product of, the Chemical of Concern, if the source(s) of the Chemical of Concern</p>

ATTACHMENT A: TOP FIVE CHANGES NEEDED

	<p>is/are one or more of the following:</p> <p>(A) A naturally occurring contaminant in raw materials that are common and are frequently used to manufacture the product;</p> <p>(A) Air or water frequently used as a processing agent or an ingredient to manufacture the product;</p> <p>(c) A contaminant in recycled materials that are common and are frequently used to manufacture the product; and/or</p> <p>(B) A processing agent or intermediate frequently used to promote certain chemical or physical changes during manufacturing, and the incidental retention of a residue is not desired or intended.</p> <p>§ 69505.3(b)(3) (B) Compare each of the alternative chemicals being considered with the Chemical(s) of Concern in the Priority Product, using the information collected and evaluated under subparagraph (A);</p> <p>(C) Eliminate from further consideration in the AA any alternative chemical(s) that the responsible entity determines poses equal or greater adverse public health and/or environmental impacts than the Chemical(s) of Concern;</p> <p>§ 69505.3 Add <u>(D)-Eliminate from further consideration in the AA any economically infeasible alternative chemical(s) which is projected to be economically infeasible at time of implementation and use.</u></p>
Three	Revise regulatory responses to be practical
	<p>§ 69506. Regulatory Response Selection Principles.</p> <p>(a) The Department shall identify and require implementation of regulatory responses designed to protect public health and the environment <u>from the harm caused by the Chemical of Concern in the Priority Product or the substitute product design required by the Department following completion of the alternatives analysis,</u> and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.</p> <p>(b) In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, “inherent protection” refers to avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a <u>Priority Pp</u> product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern in <u>the Priority Pp</u> product .</p> <p>(c) In selecting regulatory responses, the Department may consider any or all of the following factors:</p> <p>(1) The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the <u>Chemical of Concern in the Priority Pp</u> product <u>or selected substitute product;</u></p> <p>§69506.2 (b) <u>Within one year of the completion of the Alternatives Assessment, t</u>The</p>

ATTACHMENT A: TOP FIVE CHANGES NEEDED

	<p>Department may at any time require a responsible entity to obtain or develop, within a time frame specified by the Department, information to fill one or more of the information gaps identified in the Final AA Report, under section 69505.5(i)(2), if the Department determines this information is needed to re-evaluate, under section 69506.10(b), the initial regulatory response(s) imposed for a selected alternative or a Priority Product that remains in commerce.</p> <p>§ 69506.4(a)(1) Except as provided in paragraph (2), this section may apply <u>applies to a Priority Product, or a selected alternative to a products, Priority Products, containing a Chemical of Concern above the alternatives analysis threshold for which an alternative is not selected, and Priority Products.</u></p> <p>§ 69506.5 Use Restrictions on Chemical(s) of Concern and Consumer Products.</p> <p>The Department may impose restrictions on the use of one or more Chemicals of Concern in a selected alternative, or in a Priority Product for which an alternative is not selected, or restrictions on the use of the product itself, to reduce the ability of the product to contribute to or cause adverse public health and/or environmental impacts. Use restrictions may include one or more of the following:</p> <p>(a) Restrictions on the amount or concentration of the Chemical(s) of Concern permitted in a product;</p> <p>(b) Restrictions on the settings in which a product may be sold or used;</p> <p>(be) Restrictions regarding the form in which a product is sold; <u>and/or</u></p> <p>(d) Restrictions on who may purchase and/or use a product;</p> <p>(e) Requirements for training of product purchasers and/or users; and/or</p> <p>(c) Any other use restriction that reduces the amount of any Chemical(s) of Concern in the product, or reduces the ability of the product to contribute to or cause an exposure to the Chemical(s) of Concern in the product.</p> <p>§ 69506.7 (b) Engineering or administrative controls may be imposed by the Department to either integrally contain the Chemical(s) of Concern within the structure of the product or limit exposure to the Chemical(s) of Concern, if one or more of the following applies:</p> <p>(1) Reliable information indicates the presence of the Chemical(s) of Concern or, its/their degradate, metabolite, or reaction products, i in a particular subpopulation that has one or more routes of exposure to the chemical(s) <u>and where such controls are necessary to limit exposure to the chemical of concern in the consumer product.</u></p> <p>→</p> <p>§69506.8(a)(2)(A) (7) a. A financial guarantee provided by the responsible entity to insure a sustainable end of life management program for the product.</p> <p>b. “Financial guarantee” means any mechanism, including the mechanisms described in article 8 of chapter 14, to ensure that adequate funding is available to pay for future end of life management costs for products placed into the stream of commerce in California.</p> <p>§69506.8(a)(2)(B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and owners/operators of prospective collection sites. <u>That program must include mechanisms, including market-based mechanisms, to ensure that there will be funding for the costs, if any, of proper collection of the products for the period of the product’s useful life after the manufacturer ceases to exist. The collection program must include one or both of the following: 1. Collection mechanisms; and/or 2. Compensation to retailers and other</u></p>
--	--

ATTACHMENT A: TOP FIVE CHANGES NEEDED

	<p>persons who agree to administer or participate in the collection program. -</p> <p>§69506.10 (b) The Department may periodically re-evaluate any regulatory response imposed under this section to determine if changes are needed based upon changed circumstances or information identified since a regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report under section 69505.5(i)(2). The Department may accordingly require a new AA to be performed, and Preliminary and Final AA Reports to be submitted to the Department, in a specified time period -</p>
Four	Eliminate duplicative regulation
	<p>§69501(b)(4) This chapter does not apply to a consumer product regulated by one or more federal and/or California state regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that address the same adverse public health and environmental impacts that would otherwise be the basis for the product being listed as a Priority Product.</p>
Five	Set achievable reporting scope
	<p>1 - Delete AA threshold exemption notifications, chemical of concern removal notifications , and regulatory response exemption requests</p> <p>2 - Have AA Reports with reasonable parameters</p> <p>§ 69505.3 Move to § 69505.1 (a) All references in this <u>section-article</u> to “Chemical (s) of Concern” mean the Chemical(s) of Concern that is/are the basis for the product being included on the Priority Products list.</p> <p>§ 69505.4 (b)(4) Any <u>absent or</u> conflicting data regarding a relevant factor, <u>and either or both of the following, as appropriate:</u> (A) Available data that is most protective of public health and the environment, unless there are sound methodological reasons for rejecting such data; and/or (B) A value for the metric, using a method for dealing with data uncertainty due to absent or missing data that has been adopted by an authoritative organization, as defined in section 69401.2(b), or generally accepted in peer reviewed literature -;</p> <p>§ 69505.4 (b)(-8) Any other known evaluation of the Priority Product or one or more of the alternatives that comes to different conclusions, regarding the relative overall performance or public health and/or environmental impacts, and the reasons for the difference in the conclusions (-.</p> <p>§ 69505.5 (a)(5) The responsible entity shall identify and explain in the Final AA Report <u>differing conclusions from the Preliminary AA Report</u> all major differences -..</p> <p>§ 69505.5 (e)(3) Identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for the product being included on the Priority Product list <u>and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the product</u></p>

ATTACHMENT A: TOP FIVE CHANGES NEEDED

<p>3 - Delete requirements of listing customers who purchased products within the last 12 months</p> <p>§69505.5 (d)(3) The name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months ;</p> <p>§ 69505.6. (c)(2) If the Department requires one or more regulatory responses under sections 69506.5, 69506.6, 69506.7, 69506.9, and/or 69506.10, the Department shall specify in the notice the proposed due date(s) for implementation of the regulatory response(s). In assigning a due date for completing a regulatory response, the Department shall consider the complexity of implementing the regulatory response. <u>If a product design change is required, the Department shall allow sufficient time for prototype development and testing for highly durable products .</u></p> <p>4 - Extend time period to seek judicial review to enjoin disclosure of trade secret information</p> <p>§ 69510.1 (b)(2) If the submitter fails to provide the information within the timeframe specified, the Department shall notify the submitter by certified mail that the claim is out of compliance with this article, and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department sixty thirty (6030) days after such notice is mailed. During this 6030-day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief.</p> <p>(c) If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department sixty thirty (6030) days after such notice is mailed. During this 6030-day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief.</p>
--

October 11, 2012



**sierra
research**

1801 J Street
Sacramento, CA 95811
Tel: (916) 444-6666
Fax: (916) 444-8373
Ann Arbor, MI
Tel: (734) 761-6666
Fax: (734) 761-6755

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Subject: Proposed Safer Consumer Product Alternatives Regulation

Dear Ms. Von Burg:

On behalf of the Alliance of Automobile Manufacturers, we are submitting the following comments pertaining to the Department of Toxic Substances Control's (DTSC's) proposed regulation for Safer Consumer Product Alternatives.

The California Environmental Quality Act (CEQA) – Intent and General Applicability to Regulatory Programs

DTSC has prepared a draft Notice of Exemption (NOE) without performing any meaningful environmental review of the “project” as required pursuant to the California Environmental Quality Act (CEQA).

The intent of the legislature in enacting CEQA is stated at sections 21000 and 21001 of the California Public Resources Code. Of particular significance with respect to the Safer Consumer Product Alternatives Regulation are sections 21001(f) and (g), which declare that it is the policy of California to:

(f) Require governmental agencies at all levels to develop standards and procedures necessary to protect environment quality.

(g) Require governmental agencies at all levels to consider qualitative factors as well as economic and technical factors and long-term benefits and costs, in addition to short-term benefits and costs and to consider alternatives to proposed actions affecting the environment.

DTSC's position with respect to the Safer Consumer Product Alternatives Regulation does not comport with either of these policies, as evidenced by its claim that the rulemaking is exempt from CEQA. DTSC has provided no basis to support its claim that the rulemaking is exempt from CEQA, and other evidence (such as that contained in this letter) clearly indicates that it is not exempt.

First, it is clear that the Safer Consumer Product Alternatives Regulation represents a massive program with the potential to fundamentally alter the availability, composition, and nature of consumer products in California.

The California Legislature intended that this type of rulemaking be subject to CEQA. The fact that the proposed regulations will have a far-reaching effect can be seen, among other places, in the Public Notice, where DTSC states:

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, and are sold, offered for sale, distributed, supplied, or manufactured in California....

Other evidence can be seen in the press release announcing the release of the draft regulation,¹ where DTSC Director Debbie Raphael is quoted as saying:

Using a world-wide recognized list of “chemicals of concern” the regulation would create a process by which manufacturers who are using one of those listed chemicals must identify and examine the viability of safer ingredients. If an alternative is not feasible, DTSC will identify steps the manufacturer must take to ensure the product is safely used, disposed of, or phased out.

And that:

We see this as a two-for-one initiative. Public health and the environment benefits by lessening our use of toxic chemicals, and California companies get a significant boost into markets that are rapidly expanding. This regulation will stimulate growth in those markets and move us toward a higher level of environmental protection.

Both of these statements also acknowledge that the regulation will affect the environment, and the regulation should not be adopted absent consideration of all of the factors contemplated in the aforementioned CEQA provisions. In addition, they indicate that there will be a transition that will lead to both short- and long-term impacts that should also be carefully considered. Again, when read in the context of the legislative intent set forth in CEQA, these statements make it clear that this rulemaking is not exempt from CEQA compliance.

Similarly, in the Executive Summary of the economic analysis prepared in support of the proposed regulation it is noted that:

The regulations intend to improve public health and environmental quality by introducing a set of rules that will create a discovery process that will change how manufacturers produce their products and generate new information about the chemical content of products. Once the assessment

¹ California Environmental Protection Agency, Department of Toxic Substances Control, News Release, T-06-12, July 27, 2012. <http://www.dtsc.ca.gov/PressRoom/upload/News-Release-T-06-12.pdf>

is completed, firms may manufacture an alternative product if it meets prescribed conditions. Failing this, DTSC may issue a regulatory response mandating several possible actions by the firm, ranging from engaging in further research, providing product information, adopting an identified alternative, to banning products from the California marketplace.

Despite all of these statements acknowledging that the regulation has foreseeable impacts on the environment, DTSC has performed no analysis, survey, economic assessment, or other study of how parties affected by the proposed regulations will respond to the enactment of the regulation either before or after implementation. Clearly, there are some responses that could create either adverse environmental or public health impacts, such as the elimination of existing consumer products from the marketplace or the creation of bars to the introduction of new products.

Changes in chemical composition and product inputs are clearly the primary intended consequence of the regulations. Furthermore, they will inevitably result in impacts that should be considered, disclosed, and analyzed. For example, if DTSC wants to push for alternatives to certain chemicals, CEQA requires that DTSC inform itself about the supply of potential alternatives and how it might change as a result of that action. Similarly, DTSC needs to consider how chemicals are manufactured and supplied, and whether the increased manufacture of proposed alternatives might necessitate a need to expand existing facilities, construct new facilities, or could result in the manufacture or supply of alternative chemicals that pose different environmental challenges (e.g., what if the manufacturing process for a chosen alternative is more energy intensive than its predecessor?). The proposed regulation could also lead to discontinued production and/or premature disposal of existing products, with potential impacts ranging from human health impacts resulting from lack of efficacious consumer products to burdens on waste handling systems.

Another potential impact of the proposed regulations is that they could lead to adverse impacts by stalling the introduction of new, safer, and more efficient consumer products. The absence of desirable consumer products in California could result in major shifts in global supply chain logistics, as well as increased travel to bordering states and countries to purchase those products, with impacts ranging from increases in fuel usage to economic impacts associated with lost California sales and reduced sales tax revenues. Similarly, development of a new California-based consumer product industry as envisioned by Director Raphael could lead to dramatic increases in goods movement in California. As is well known, goods movement can have serious environmental and public health consequences and has resulted in significant concerns regarding “environmental justice” in many California communities.

We therefore request that DTSC suspend finalization of the regulatory proposal until a CEQA Initial Study can be performed, followed by the appropriate level of CEQA review, which is the preparation of a Program Environmental Impact Report (Program EIR).

Improper Avoidance and/or Deferral of CEQA

First, it is important to highlight that it appears that DTSC is simply trying to avoid CEQA compliance at both “program” and “project” levels by any means possible. As discussed below, DTSC’s attempt to avoid CEQA compliance at the program level is two pronged. First, DTSC claims that a statutory exemption applies, and then DTSC also claims that a common sense exemption applies. However, both arguments fail because DTSC attempts to support them based on arguments related to “project” specific as opposed to “programmatic” analyses.

Next, DTSC similarly attempts to claim that the actions taken in response to the implementation of the proposed regulations are also exempt from CEQA because the structure of the regulation will ensure that there are no adverse environmental impacts associated with any action taken. However, as discussed in detail below, in fact the proposed regulation contains no mechanism that will ensure compliance with CEQA even at the “project” level.

At this point in the regulatory process, the key issue is DTSC’s failure to address CEQA from a “programmatic” standpoint. Evidence of how DTSC is trying to avoid compliance with CEQA at the program level can be found in many places, for example, on page six of the NOE. Here DTSC states, “In addition, there will be no physical change in the environment resulting from this action on the part of DTSC to adopt regulations that specify a **process** for identifying and prioritizing COCs in consumer products, since the activities being conducted by DTSC are intellectual evaluation and analysis only.”² [Emphasis in original.]

It is also unclear how DTSC can support this broad and general statement given that DTSC has not identified which scientifically vetted process(es) will be utilized in the identification or prioritization process for COCs. Given the of lack of an identified process, affected industries cannot even perform a rudimentary analysis of potential chemical changes, the environmental impact of those changes, and the subsequent impacts to the citizens and environment of the State of California. It simply isn’t credible for DTSC to claim that there will no environmental impacts associated with the proposed regulation.

DTSC grossly errs by attempting to limit the scope of environmental review required by CEQA to only the agency’s own administrative activities, thereby ignoring any “real world” activities that will be undertaken by the regulated parties as a result of the regulatory program. DTSC implies that the “project” consists merely of DTSC’s “intellectual evaluation and analysis” (i.e., Department employees administering the program in an office environment). This logic undercuts the entire intent of CEQA. In doing so, DTSC even misrepresents the project by failing to describe the regulatory responses that can and will stem from their analysis. Under this faulty logic, Lead Agencies could approve large and significant projects (such as new refineries, new hazardous waste disposal sites, or new large developments) under the auspices that no

² Draft NOE available at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-CEQA-NOE-7-26-12.pdf>

impacts would occur as a result of the day-to-day job duties of Lead Agency employees, which consist only of reviewing documents and drafting permits.

Elsewhere in the draft NOE, DTSC states that “the need for additional CEQA evaluation will be considered, as appropriate, during implementation of the regulatory program.” While we agree that further CEQA evaluation will be necessary at further implementation stages of DTSC’s Safer Consumer Products regulatory program (likely as tiered CEQA documents subsequent to a Program EIR), the potential significant impacts should be disclosed to the public at this time via a Program EIR.

Section 15168(a)(3) of the CEQA Guidelines describes a Program EIR as, “...an EIR which may be prepared on a series of actions that can be characterized as one large project and are related [...] in connection with the issuance of rules, regulations, plans, or other general criteria to govern the conduct of a continuing program.” Section 15164 requires that Program EIRs be prepared for phased projects where the total undertaking causes a significant environmental effect. The same section further requires that, “Where an individual project is a necessary precedent for action on a larger project, or commits the Lead Agency to a larger project, with significant environmental effect, an EIR must address itself to the scope of the larger project.”

In this case, DTSC is seeking to defer the environmental analysis of the Safer Consumer Products program to later stages in its implementation, or to avoid CEQA review altogether. DTSC simply has to abandon this approach and suspend further action to finalize the Safer Consumer Products regulation until an Initial Study and further environmental review is performed. We believe that the Initial Study will show that the preparation of a Program EIR is required at this time, and that future project-level CEQA review of DTSC’s subsequent actions will be required as described in Section 15152 of the CEQA Guide, pertaining to “tiering.”

In contrast to DTSC’s unvarnished attempt to avoid CEQA compliance, there are a multitude of examples that demonstrate how California regulatory agencies need to address the requirements imposed by CEQA for projects like the Safer Consumer Product Alternatives regulations. Perhaps the most germane example is the AB32 program being implemented by the California Air Resources Board (CARB). The AB32 Scoping Plan and its Appendices³ provide all of the information required to assess the environmental and public health impacts of the AB32 program, including but not limited to assessments of how technical and economic factors may create adverse impacts as well as the complete functional equivalent of a CEQA analysis, which is contained in Appendix J of the Scoping Plan document.

The CEQA analysis performed for the Scoping Plan is programmatic and looks at the broader environmental and public health impacts of a regulatory structure, not the specific impacts of individual actions. CARB explicitly acknowledges both the need for and the appropriateness of a programmatic CEQA analysis, stating in Appendix J that:

³ *Climate Change Scoping Plan, a Framework for Change*, prepared by the California Air Resources Board, December 2008.

This analysis is necessarily programmatic. It will provide a basis for future environmental analyses and allows future project-specific environmental analysis to focus solely on the new effects or detailed environmental issues not previously considered. A program environmental document allows consideration of broad policy alternatives and program wide mitigation measures at a time when an agency has greater flexibility to deal with basic problems of cumulative impacts. A programmatic document also plays an important role in establishing a structure within which future reviews and related actions can effectively be conducted.

It is also important to note that CARB could have attempted to argue (as DTSC has with respect to the Safer Consumer Product Alternatives regulations) that the Scoping Plan was exempt from CEQA because it was just an intellectual exercise, and that there could never be an action taken pursuant to AB32 that would result in adverse environmental or public health impacts. However, CARB recognized that to do so would not have been reasonable, nor would it have satisfied the requirements of CEQA. It should also be noted that in addition to the Program EIR prepared by CARB, the specific actions taken in the implementation of the Scoping Plan are also subject to the functional equivalent of a project level CEQA analysis.

The Rulemaking Does Not Qualify for a Statutory Exemption under CEQA

The 45-day Public Notice for the rulemaking states that DTSC has found the action to be exempt from CEQA. Specifically, the Public Notice states, "This rulemaking meets the statutory exemption available under subdivision (b)(8) of Public Resources Code section 21080." The Public Notice again notes that a draft NOE has been prepared, which will be filed with the State Clearinghouse upon adoption of the regulation.

The statutory exemption cited by DTSC is completely unrelated to the rulemaking and is not applicable. Public Resources Code § 21080(b)(8), and the corresponding CEQA Guidelines found in 14 CCR § 15273, pertain to public agency actions that establish "rates, tolls, fares, and charges." The Statute and Guidelines provide for a full CEQA exemption for only five specific rate/toll/fee/charge actions, with all other rate-related actions being non-exempt and subject to CEQA review. Furthermore, the Guidelines require that the public agency make written findings (and highlight them) in the record to support the claim that the exemption applies.

We would note that the NOE makes no reference to this statutory exemption and contains no written findings to support the exemption claim in the Public Notice. Because the proposed rulemaking does not entail the establishment of a rate, toll, fee, or charge, this statutory exemption has been erroneously applied. We therefore request that DTSC abandon its claim that the rulemaking is exempt from CEQA, and commence with the preparation of an Initial Study to determine the proper level of CEQA review required for this rulemaking, which is a Program EIR.

It is expected that DTSC will respond to the above by stating that it meant to claim a statutory exemption under subdivision (b)(9) of Public Resources Code section 21080

rather than subdivision (b)(8). However, as is documented in detail below, the criterion for this exemption, which is that the proposed project can be determined not to have a significant impact on the environment, simply cannot be satisfied given the scope and foreseeable impacts of the proposed regulation.

The Rulemaking Does Not Qualify for CEQA's "Common Sense" Exemption

The draft NOE reaches the conclusion that the exemption described in 14 CCR § 15061(b)(3) of the CEQA Guidelines, which has been referred to by the courts as the "common sense exemption," applies to the project, and therefore no further environmental review is necessary.

The rationale behind CEQA's common sense exemption is that "CEQA applies only to projects which have the potential for causing a significant effect on the environment." The exemption further states that, "Where it can be seen with certainty that there is no possibility that the activity in question may have a significant effect on the environment, the activity is not subject to CEQA."⁴

The CEQA Guidelines specify that if an agency finds a project to be exempt from CEQA and prepares and files a NOE, the NOE shall include a brief statement of reasons to support the finding of an exemption. The draft NOE prepared by DTSC purports to include such a statement of reasons; however, all of the given reasons oddly contravene the common sense exemption. Specifically, the NOE makes the following statements [emphasis added]:

*The task of analyzing whether there could be a significant effect on the environment...is **incredibly speculative.***⁵

*Evaluating the effects...and the environmental impact...is both **infeasible and unreasonably speculative.***⁶

*Consequently, it is **virtually impossible** at this point of adoption of the regulations for DTSC to engage in any meaningful evaluation of the significant environmental impacts, **if any**, that may result from the implementation of the regulations.*⁷

It is clear from the draft NOE that DTSC is anything but certain about the level of effects its action will have on the environment. DTSC's conclusion that further analysis and evaluation of the rulemaking is "speculative," "infeasible," and "virtually impossible" contravenes the language of the exemption, which requires "certainty" that "no possibility" of a significant environmental effect will occur.

⁴14 CCR § 15061(b)(3)

⁵ Draft NOE, Page 5

⁶ Draft NOE, Page 6

⁷ Ibid.

Again, all of the above rationales put forth by DTSC apply to “project” specific impacts resulting from actions that could be taken if the proposed regulations are enacted, not “programmatic” impacts that can currently be foreseen, analyzed, and for which mitigation can be proposed. That is exactly the purpose of a Program EIR.

In *Davidon Homes v. City of San Jose*, the Court found⁸ that, “In the case of the ‘common sense’ exemption, [...] the agency’s exemption determination is not supported by an implied finding by the Resources Agency that the project will not have a significant environmental impact. Without the benefit of such an implied finding, ***the agency must itself provide the support for its decision*** before the burden shifts to the challenger. Imposing the burden on members of the public in the first instance to prove a lack of environmental impact would frustrate CEQA’s fundamental purpose of ensuring that government officials ‘make decisions with environmental consequences in mind.’” [Emphasis added.]

In the same decision, the Court added, “An agency’s obligation to produce substantial evidence supporting its exemption decision is all the more important where the record shows, as it does here, that opponents of the project have raised arguments regarding possible significant environmental impacts.”

Even though DTSC’s draft NOE fails to provide any support for using CEQA’s common sense exemption (and hence no burden is borne by the public to prove that DTSC’s action will cause significant environmental impacts), the following sections of these comments describe potential significant environmental impacts that may occur from DTSC’s rulemaking. These should be considered by DTSC in the preparation of an Initial Study to determine the proper level of CEQA review required for this rulemaking, which is the preparation of a Program EIR.

Foreseeable Direct and Indirect Effects of DTSC’s Safer Consumer Products Alternatives Regulatory Program

As is outlined below, it is simply not credible for DTSC to conclude that (1) there is no possibility of significant environmental effect due to the rulemaking, and (2) evaluation of such impacts is infeasible or impossible at this stage of the program’s development. DTSC characterizes the rulemaking as “a four-step, science-based, iterative process.”⁹ The four steps in this process are outlined below.

1. DTSC specifies a list of Chemicals of Concern (COC).
2. DTSC evaluates and prioritizes COCs to develop a list of Priority Products.
3. Regulated parties that produce or introduce Priority Products into commerce must conduct a Preliminary and Final Alternatives Analysis Reports to DTSC.

⁸ *Davidon Homes et al, Plaintiffs and Appellants v. City of San Jose, Defendant and Respondent*, 54 Cal.App.4th 106, No. H0150182. California Court of Appeal, Sixth District. April 9, 1997, Available at <http://ceres.ca.gov/ceqa/cases/1997/davidon.html>, Accessed: September 13, 2012.

⁹ Pages 2 and 4.

4. DTSC will impose one or more of the following regulatory responses:
- No action is required;
 - The regulated party must provide product information for consumers;
 - Use of the COC in consumer products is restricted;
 - Sale of specific products is prohibited;
 - Engineered safety or administrative controls are required;
 - An end-of-life product management program is required; and/or
 - Funding of research and development projects is required.

In its Initial Statement of Reasons (ISOR),¹⁰ DTSC only begins to consider the results of the above four-step process. On page 4 of the ISOR, DTSC includes the following statements:

DTSC has determined that the regulation may result in the creation of new businesses as new materials and processes are created. ...

DTSC has determined that the regulation provides opportunities for growth as California businesses have access to wider range of safer consumer products and can provide services and products for an expanding number of consumers demanding safer and greener products.

The above statements indicate that DTSC believes that the regulation will result in new activities within California related to “new materials” and “new processes.” Specifically, these effects are most likely to occur at Steps 3 and 4 above, but could indirectly occur at Steps 1 and 2 as well. Upon DTSC identifying one or more Priority Products (Step 2), it is foreseeable that the responsible entity will either undertake a voluntary redesign or reformulation of the Priority Product to eliminate the COC, or they will proceed to Step 3 and prepare the mandatory Preliminary Alternatives Analysis report. If the COC is not voluntarily removed from the Priority Product, DTSC may take one or more of the above regulatory responses, which include a mandate that the Priority Product be redesigned or reformulated.

The direct effects of redesigning and reformulating Priority Products (whether voluntary or mandatory) are foreseeable. Presumably, an economic benefit was realized by the manufacturer in using the COC in the first place. The economies of using the COCs could result from its obtainability from local sources, the ease and simplicity of its use in the manufacturing process, and the overall efficacy and utility of the final product containing the COC. Conversely, a redesigned or reformulated Priority Product is likely to require raw materials that are less easy to obtain (i.e., raw materials imported from more distance locations), require a more difficult or intensive manufacturing process, and/or result in a less effective product. Each of these foreseeable results will result in energy and environmental impacts that require evaluation under CEQA.

¹⁰ Initial Statement of Reasons, Safer Consumer Products. Department Reference Number: R-2011-02. Office of Administrative Law Notice File Number: Z-2012-0717-04. Available at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>

Additional direct effects could occur as part of the final two regulatory responses. Under the first of these, a manufacturer could be required to implement an end of life product management program. It is foreseeable that such a program could require the establishment of collection centers throughout California. Collected consumer products likely would require special handling and storage procedures, and may require disposal as hazardous wastes, thereby increasing the volume of material diverted to hazardous waste disposal sites. Likewise, the final regulatory response would require the funding of special research and development projects. It is foreseeable that these projects could entail the construction and operation of new research and testing facilities; increased product performance and toxicological testing (including animal testing); and waste streams associated with destructive testing, spent reagents, and construction and disposal of prototypes.

The indirect effects of listing COCs and Priority Products are equally foreseeable. These include manufacturers' desire to avoid a costly alternatives assessment process; manufacturers' perceived increase in product liability if sales continue during the alternatives assessment process; and heightened public concern, avoidance, or aversion of COCs and Priority Products in their possession. It is foreseeable that a manufacturer, upon DTSC's publishing of a COC list, or having their product deemed a Priority Product, may voluntarily redesign or reformulate the product to avoid further requirements under the Safer Consumer Products Alternatives Regulation. The proposed regulation attempts to "catch" these voluntary substitutions through an after-the-fact "Priority Product Replacement Notification." However, even if the replacement notification is submitted for voluntary substitutions, there is no follow-up requirement for an Alternatives Analysis under the rule, and therefore, the substitution can still be performed without any assurance that "adverse public health and/or environmental impacts," as defined in the proposed rule, would be avoided.¹¹ Because the replacement notification occurs after the fact (within 30 days after the replacement product is introduced into commerce), the environmental impacts have already occurred prior to DTSC even being notified of the action.

Also, indirect impacts are possible if replacement parts are not available for consumer products already in commerce. For example, if a manufacturer of automobile replacement parts ceases to produce certain replacement parts rather than redesign them to eliminate COCs, consumers will be faced with no means to repair their vehicles. This could lead to a large increase in the number of vehicles scrapped in California or shipped out of the state where replacement parts would still be available, which in turn would lead to numerous potentially significant environmental impacts. These begin with the impacts associated with the increased production of new vehicles needed to replace vehicles that can no longer be operated in California. Foreseeable environmental impacts include resource extraction (e.g. mining and other activities) required to obtain the raw materials required for vehicle production, and environmental impacts associated with vehicle production which include increases in emissions of greenhouse gases and traditional air

¹¹ We note that the rule's definition of "adverse public health/environmental impacts" is limited to toxicological, air quality, ecological, soil, and water quality impacts, or, an exceedance of an enforceable federal or California regulatory standard pertaining to public health or the environment. This definition is reduced in scope from the definition of a "significant effect on the environment" as defined in CEQA, and therefore, does not preclude the occurrence of significant CEQA impacts even if no "adverse public health and/or environmental impacts" occur under the proposed regulation.

pollutants as well as adverse socioeconomic impacts to low income communities where the loss of access to transportation by personal vehicles would likely lead to substantial losses in jobs.

Another foreseeable impact is that although DTSC's Safer Consumer Product Alternatives Regulation is intended to apply only to the "responsible entities" introducing COCs and Priority Products into California commerce, the regulation could in effect cause a "voluntary recall"—that is, once DTSC identifies a COC or Priority Product, the public and/or retail sellers may feel the need to spontaneously dispose of existing COCs and Priority Products already in commerce. This may cause a surge in that chemical/product being directed to landfills prior to implementation of end-of-life procedures. A related impact could be a substantial reduction in the degree to which products with COCs and Priority products are recycled because of similar concerns.

Foreseeable Significant Environmental Impacts Arising from DTSC's Regulatory Program for Safer Consumer Product Alternatives

CEQA defines a significant effect on the environment as "a substantial adverse change in the physical conditions which exist in the area affected by the proposed project."¹² Appendix G ("Environmental Checklist Form") of the CEQA Guidelines contains sample questions to be used by lead agencies when conducting Initial Studies. The Environmental Checklist Form notes, "The sample questions in this form are intended to encourage thoughtful assessment of impacts, and do not necessarily represent thresholds of significance," although projects that are found to have "potentially significant impacts" per the form generally require the preparation of an EIR.

Table 1 lists a multitude of foreseeable significant environmental impacts associated with the proposed Safer Consumer Product Alternatives Regulation that should be addressed by the preparation of a Program EIR. DTSC should consider all of these foreseeable impacts, as well as others, when conducting an Initial Study and further environmental review of the proposed Safer Consumer Product Alternatives Regulation. Again, we believe that the result of the Initial Study will show that numerous potentially significant environmental impacts are foreseeable, and that a Program EIR must be prepared pursuant to CEQA.

¹² 14 CCR 15002(g)

Table 1	
Examples of Foreseeable Significant Environmental Impacts	
Environmental Factor	Foreseeable Effect of Safer Consumer Product Alternatives Regulation
Air Quality	<ul style="list-style-type: none"> • Construction activities associated with new facilities and with expansion of existing facilities producing COC and/or Priority Product alternatives will result in <u>localized</u> increases in fugitive dust, criteria pollutant emissions and air toxics emissions in excess of established thresholds of significance. • Operational activities of new and/or expanded facilities producing COC and/or Priority Product alternatives will result in <u>localized</u> increases in fugitive dust, criteria pollutant emissions and air toxics emissions in excess of established thresholds of significance. • Construction activities associated with new facilities and with expansion of existing facilities producing COC and/or Priority Product alternatives will result in <u>regional</u> criteria pollutant emission increases in excess of established thresholds of significance. • Operational activities associated with new facilities and with expansion of existing facilities producing COC and/or Priority Product alternatives will result in <u>regional</u> criteria pollutant emission increases in excess of established thresholds of significance. • New or modified manufacturing processes for COC and/or Priority Product alternatives could create objectionable odors in excess of established thresholds of significance. • The above impacts, when combined with the effects of other past, current, and foreseeable projects, will be cumulatively significant. • New or modified manufacturing processes for COC and/or Priority Product alternatives could create objectionable odors in excess of established thresholds of significance. • The above impacts, when combined with the effects of other past, current, and foreseeable projects, will be cumulatively significant.
Greenhouse Gas Emissions	<ul style="list-style-type: none"> • Construction activities of new and/or expanded facilities producing COC and/or Priority Product alternatives will result in GHG emissions in excess of thresholds of significance. • Operational activities of new, expanded, and/or modified facilities producing COC and/or Priority Product alternatives will result in GHG emissions in excess of thresholds of significance. • New and/or substitute raw materials for COC and/or Priority Product alternatives have associated lifecycle GHG emissions in excess of thresholds of significance.

Table 1	
Examples of Foreseeable Significant Environmental Impacts	
Environmental Factor	Foreseeable Effect of Safer Consumer Product Alternatives Regulation
	<ul style="list-style-type: none"> • New or modified manufacturing processes producing COC and/or Priority Product alternatives are more energy intensive, resulting in an increase in GHG emissions that exceeds a threshold of significance.
Hazards & Hazardous Materials	<ul style="list-style-type: none"> • New and/or modified manufacturing processes create new streams of hazardous materials as a result of either removing COCs from Priority Products or from more complex manufacturing techniques required under alternatives assessments. • Mandated end-of-life procedures create new (or consolidated) waste streams that require enhanced handling procedures and/or special disposal sites. • Listing of COCs or Priority Products triggers voluntary disposal of such chemicals or products by the public, thus increasing the occurrence of COCs in normal waste streams. • Manufacturers voluntarily substitute listed COCs with non-listed chemicals outside of the DTSC's alternatives assessment process to avoid further regulation.
Hydrology/Water Quality	<ul style="list-style-type: none"> • New and/or modified manufacturing processes are more water intensive or create additional industrial wastewater volumes as a result of either removing COCs from Priority Products or from more complex manufacturing techniques required under alternatives assessments. • Mandated end-of-life procedures create new (or consolidated) waste streams that require enhanced handling procedures and/or special disposal sites that potentially increase wastewater volumes and/or affect groundwater quality near disposal sites. • Listing of COCs or Priority Products triggers voluntary disposal of such chemicals or products by the public, thus increasing the occurrence of COCs in normal waste streams and degrading groundwater quality in the vicinity of disposal sites. • Manufacturers voluntarily substitute listed COCs with non-listed chemicals outside of the DTSC's alternatives assessment process to avoid further regulation, resulting in increased industrial wastewater streams and/or degraded water quality in the vicinity of disposal sites for industrial solid wastes.

The Rulemaking's Internal Reduced-Scope Environmental Review Process is Not CEQA-Equivalent and Does Not Prevent Significant Environmental Impacts

Although the comments presented above focus on why DTSC must prepare a Program EIR for the proposed regulation, it is also clear that DTSC's claims that the provisions of the proposed regulation will satisfy CEQA at the project level are also incorrect.

The proposed regulation incorporates a scaled-back environmental review process within its Alternatives Analysis (AA) requirements. The first stage of the AA process requires responsible entities to "Collect and use available information on hazard traits and toxicological and environmental endpoints, and any other relevant data, to identify all of the following for each alternative chemical being considered." These data are limited to information on "adverse public health impacts," "adverse environmental impacts," "environmental fate," "physical chemical hazards," and "physicochemical properties."¹³ For each alternative chemical being considered, the responsible entity is then to "compare" the alternative chemical to the COC in the Priority Products, and then "eliminate any alternative chemical(s) that the responsibility entity determines poses equal or greater adverse public health and/or environmental impacts than the Chemical(s) of Concern."¹⁴

The second stage of the AA process requires responsible entities to "collect and use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed in subparagraph (A) and, where applicable, the associated exposure pathways and life cycle segments that are relevant for the comparison of the Priority Product and the alternatives still under consideration after completion of the first AA stage as specified in section 69505.3"¹⁵ The factors identified in subparagraph "A" are the "multimedia life cycle impacts and chemical hazards for chemical ingredients known to be in the Priority Product and alternatives being considered" regarding the same seven factors previously listed under the first AA stage. The results of this analysis are to be considered in the alternative selection decision and documented in the AA report.

There are two reasons why the process outlined in DTSC's proposed regulation is not equivalent to a project level CEQA review and does not prevent significant environmental impacts as defined in CEQA. First, the AA process lists only the seven broad factors (listed above), and completely overlooks the numerous environmental factors that must also be evaluated under CEQA. For example, DTSC's process requires no direct review of environmental impacts pertaining to aesthetics, agriculture and forestry resources, cultural resources, geology, hydrology, land use and planning, mineral resources, noise, population and housing, public services, recreation, transportation and traffic, and utilities and service systems. Any one of the foreseeable effects of the regulation described previously could create impacts related to the above DTSC-neglected factors.

Second, for those environmental factors that do require review under both DTSC's review process and CEQA, the review under CEQA is much more rigorous and

¹³ Proposed § 69505.3(b)(3)(A)

¹⁴ Proposed § 69505.3(b)(3)(B) and (C)

¹⁵ Proposed § 69505.3(b)(4)a(2)

comprehensive. DTSC's process requires some level of disclosure of "adverse environmental impacts," but these impacts are defined only in a cursory manner that sidesteps the concept of a "thresholds of significance" found in CEQA.

For example, "adverse environmental impact" is expanded to mean adverse impacts pertaining to air quality, ecology, soil quality, and water, or any exceedance of an enforceable California or federal environmental regulatory standard. Looking at just one of those, the term "adverse air quality impact" is simply defined as "emissions" of certain air pollutants that are listed in the regulation.

What is entirely missing from this process is the concept found in CEQA that there is a certain level of impacts above which environmental damage would occur, and below which environmental damage would be less than significant (i.e., a threshold of significance). Under CEQA, these thresholds are typically set by the public agencies responsible for the resource being evaluated. The thresholds usually are based on existing environmental standards and are contained in detailed guidelines of evaluation and implementation. Under CEQA, these public agencies most oftentimes have the ability to review and comment on the impacts analyses and significance determination as "trustee agencies," "responsible agencies," and "commenting agencies." Likewise, the public has the ability to review and comment on the environmental analysis and the impacts concerning significance. Furthermore, the CEQA process provides for the application of enforceable mitigation measures that can eliminate or significantly reduce impacts.

In contrast, DTSC's process is closed to other resource agencies and the public. Determinations of adverse environmental impacts are left primarily to the responsible entity, with review oversight by DTSC. Also in contrast to CEQA, there is a decided advantage for responsible entities to identify significant environmental impacts with product alternatives—to the end that they are not required to implement those alternatives.

Therefore, as shown above, DTSC's reduced-scope and closed environmental review process is not a substitute for CEQA review. Again, the only appropriate course of action is for DTSC to suspend its effort to finalize the regulation until a CEQA Initial Study can be performed to determine the appropriate level of environmental review that is required, which is the preparation of a Program EIR.

A Multimedia Life Cycle Evaluation is Required under H&S Code §25252.5 and the October 27, 2010 Finding by the Environmental Policy Council Is Not Relevant

Health and Safety Code section 25252.5 requires DTSC to prepare, and submit to the Environmental Policy Council (EPC), a multimedia life cycle evaluation of the proposed Safer Consumer Product Alternatives Regulation unless the EPC conclusively determines that the regulations will not have any significant adverse impact on public health or the environment.

As you are aware, DTSC previously submitted an earlier Safer Consumer Product Alternatives regulation to the EPC, which on October 27, 2010, resolved that those proposed regulations met the statutory requirement of H&S Code 25252.5(f), and therefore no multimedia environmental life cycle assessment was required. The EPC's determination was based on a September 2010 draft of the regulation which was formally withdrawn by DTSC. The version of the regulation evaluated by the EPC was filed in the September 17, 2010 edition of the *California Regulatory Notice Register* as Notice File No. Z-2010-0908-01. Subsequently, DTSC released a set of "15-day changes" to the regulation on November 16, 2010, and added seven "peer review" comments to the file plus the EPC's October 27, 2010 Resolution. As shown in the strikeout/underline version of the November 16, 2010 proposal, the regulation had been re-written almost in its entirety.¹⁶ Even though the scope of those changes far exceeded what is permitted under the 15-day change process, DTSC's action was later rendered moot by its own abandonment of the original proposal on August 1, 2011, followed by the publishing of a "Notice of Decision Not to Proceed" on August 12, 2011, in the *California Regulatory Notice Register* at page 1303. By formally abandoning the previous rulemaking, DTSC vacated all of its previous rulemaking activities, including the EPC's resolution.

On October 31, 2011, DTSC renewed its efforts to adopt a Safer Consumer Product Alternatives regulation by releasing a new, informal draft version of the regulation, followed by yet another version on May 18, 2012. A further version was released as a formal regulatory proposal on July 27, 2012, along with a five-page summary of changes since the October 31, 2011 informal draft version.¹⁷ Therefore, DTSC cannot now rely on a finding made by the EPC two years ago with respect to a fundamentally different and now-abandoned regulation—to do so would completely undermine the Legislature's intent for DTSC to conduct a multimedia life cycle evaluation of the actual regulation being adopted pursuant to the statutes. Given this, DTSC must suspend its effort to finalize the currently proposed Safer Consumer Product Alternatives Regulation until the multimedia life cycle evaluation required by H&S Code 25252.5 can be completed.

As discussed above, DTSC previously sought to avoid the multimedia life cycle evaluation envisioned by the Legislature by obtaining a decision from the EPC that a now-abandoned proposed regulation "will not have any significant adverse impact on public health or the environment." In addition to having no relevance to the currently proposed regulation, EPC's prior decision was flawed, for the reasons discussed below.

First, the EPC relied on the proposed regulation's internal alternatives analysis process, which, as we discussed in the preceding section, is limited in scope and woefully inadequate in preventing all possible significant environmental impacts from occurring.

Second, the EPC partially based its Resolution on the following finding:

¹⁶ Available at URL:

http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA_Regs_15Day_Revisions_11162010.pdf, Accessed September 25, 2012.

¹⁷ Available at URL: <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsChangesJuly2012.pdf>, Accessed September 25, 2012.

WHEREAS, DTS's eventual implementation of the proposed regulations may result in potential impacts to human health or the environment; however, because it is impossible for the Council to know at this time what chemicals or products might be affected by a future action by DTSC in accordance with the regulations, any such potential human health or environmental impacts are speculative and not reasonably foreseeable.

Here, the EPC admits that the (formerly) proposed regulation “may result in potential impacts to human health and the environment.” However, the EPC deemed those impacts to be “speculative and not reasonable foreseeable.” After making this finding, the EPC should have simply resolved that they could not “**conclusively** [determine] that the regulation **will not have any significant adverse impact on public health or the environment**” as required by H&S Code §25252.5(f). [Emphasis added.]

Inexplicably, however, the EPC nonetheless stated that it “conclusively determines that the regulations will not have any significant adverse impact on public health or the environment.” The EPC’s finding quoted above for all intents and purposes is an attempt to eliminate the multimedia life cycle evaluation requirement in the statute on the basis that the Legislature is requiring an analysis that is overly speculative and unreasonable. Rather than attempting to circumvent the statute, EPC should instead have directed DTSC to undertake the multimedia life cycle evaluation required by H&S Code 25252.5.

Two Examples of Product Substitutes Resulting in Adverse Environmental Impacts

Provided below are two examples of cases in which product substitutes resulted in adverse environmental impacts. The impacts identified below are examples of both the need for the preparation of a Program EIR for the proposed regulation, as well as the need for the processes that will result from the implementation of the regulation to be clearly subject to project level CEQA requirements. Each of these examples represents an environmental impact that should be disclosed to the public in general via the framework set out in the Program EIR as well as in detail in a project level EIR.

MTBE as a Substitute for Tetraethyl Lead in Reformulated Gasoline – Prior to the full phase-out of leaded gasoline on January 1, 1996, tetraethyl lead was added to motor gasoline as an anti-knocking agent (i.e., an octane booster). To replace lead, methyl tert-butyl ether (MTBE) was added to gasoline as oxygenate and substitute octane booster. MTBE was also found to substantially reduce CO, VOC, and NOx emissions from gasoline engines.

With the goal of reducing ambient CO levels in nonattainment areas, Section 211(m) of the Clean Air Act (CAA) requires minimum oxygen content in gasoline in certain areas with high ambient CO “design values.” The California Air Resources Board (CARB) and the U.S. Environmental Protection Agency (EPA) implemented the minimum oxygen requirements (2.7 percent oxygen by weight) in certain areas beginning in November 1992. With the goal of reducing NOx, VOC, and toxic air contaminant emissions,

Section 211(k) of the CAA, as implemented by CARB and EPA, required that gasoline be reformulated to contain a minimum oxygen content of 2.0 percent on a year-round basis in all areas effective January 1, 1995. This oxygen content mandate was later repealed in 2006.¹⁸ Collectively, these requirements (among others) are known as the federal reformulated gasoline (RFG) program.

The federal RFG program approved several compounds to be used as oxygenates in RFG, including MTBE, tertiary amyl methyl ether (TAME), ethyl tertiary butyl ether (ETBE), di-isopropyl ether (DIPE), ethanol, and tert-butyl alcohol (TBA). Of these, MTBE became the oxygenate of choice due to its substantial reductions in emissions, coupled with its availability, economics, and logistics of production and distribution, as well as drawbacks associated with the other oxygenates (particularly ethanol).

However, after the University of California prepared a comprehensive report assessing the environmental and health impacts of MTBE, concern arose over the presence/threat of MTBE in groundwater and municipal water wells originating from leaking underground storage tanks. As a result, then-Governor Gray Davis ordered that MTBE be removed from gasoline by December 31, 2002, due to a “significant risk to the environment.”¹⁹ This phase-out date was later pushed back by one year (except in the Lake Tahoe Region) due to the unavailability of ethanol in significant quantities.²⁰

The example of MTBE in reformulated gasoline clearly shows how a substitute chemical of concern caused significant adverse tradeoff environmental impacts. In the case of MTBE, those impacts were discovered after the fact, and after damage to the environment had already occurred. Reversing the use of MTBE proved to be a difficult and lengthy process. Had a full, multimedia evaluation of MTBE been conducted earlier, MTBE likely would not have gained approval as a gasoline oxygenate and long-term impacts could have been avoided. In the same manner, DTSC’s proposed Safer Consumer Product Alternatives Regulation warrants a CEQA Program EIR that will provide for future tiered analyses of any approved COC or Priority Product alternatives, or other regulatory responses.

Replacement of Perchloroethylene with VOC-Based Dry Cleaning Solvents – In 2007, CARB amended its perchloroethylene (perc) airborne toxic control measure (ATCM) to phase out the use of perc in commercial dry cleaning machines by 2023. The impetus for the phase-out was a prior finding that perc is a toxic air contaminant and that residual risk remained after prior efforts implementing best available control technology on dry cleaning machines. The ISOR for the Perc ATCM²¹ envisioned that hydrocarbon solvents (containing VOCs) would replace perc (a VOC-exempt compound) in California. In the ISOR, CARB noted the trade-off impact related to increased VOC emissions.

¹⁸ 71 FR 26691, May 8, 2006

¹⁹ Executive Order D-5-99

²⁰ Executive Order D-52-02

²¹ California Air Resources Board, Staff Report: Initial Statement of Reasons for the Proposed Amendments to the Control Measure for Perchloroethylene Dry Cleaning Operations and the Adoption of Requirements for Manufacturers and Distributors of Perchloroethylene, December 8, 2006, Available at URL: <http://www.arb.ca.gov/regact/2007/perc07/isor.pdf>, Accessed September 17, 2012.

As previously mentioned, increased usage of hydrocarbon solvents will lead to increased VOC emissions. VOC emissions contribute to the formation of ozone. Ozone formation in the lower atmosphere results from a series of chemical reactions between VOCs and nitrogen oxides in the presence of sunlight.

Ozone adversely affects the respiratory functions of humans and animals. Human health studies show that short-term exposure to ozone injures the lung. In some animal studies, permanent structural changes with long-term exposures to ozone concentrations considerably above ambient levels were noted; these changes remain even after periods of exposure to clean air. Ozone is a strong irritant that can cause constriction of the airways, forcing the respiratory system to work harder in order to provide oxygen to the body. Ozone is a powerful oxidant that can damage the respiratory tract, causing inflammation and irritation, and induces symptoms such as coughing, chest tightness, shortness of breath, and worsening of asthma symptoms. Ozone in sufficient doses increases the permeability of lung cells, rendering them more susceptible to toxins and microorganisms.

Despite the increase in VOC emissions, and the potential for higher ambient ozone levels, the amended Perc ATCM was approved. The ISOR contained an abbreviated functionally equivalent CEQA analysis that identified the adverse air quality impact (among other impacts). DTSC's proposed Safer Consumer Products Regulation is likely to entail similar trade-off impacts which require evaluation under CEQA. We therefore request that DTSC prepare an Initial Study, followed by the appropriate level of CEQA review, which is a Program EIR.

Examples of Potential Environmental Impacts from Prior Alternatives Assessments

The potentially significant environmental impacts identified in Table 1 and the need for them to be addressed by DTSC both in a Program EIR as well as in a process subject to CEQA after implementation of the proposed regulation can be further illustrated by examining prior instances of product substitution and also from the many alternatives assessments prepared by various entities. Although not mentioned anywhere in DTSC's ISOR, EPA's Design for the Environment Program (DfE) provides a process whereby manufacturers may subject their products to an evaluation process to assess that product's potential to expose humans to toxic compounds or to impact the environment. DfE also includes an Alternatives Assessments Program whereby environmental organizations, industry leaders, academia, and others form partnerships to evaluate the environmental and health impacts of potential alternatives to problematic chemicals. Under this program, products are evaluated according to EPA's *Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation*. Chapter 4.2.2 of the Alternatives Assessment Criteria provides criteria for evaluating the environmental persistence of chemicals with regard to persistence in water, soil, or sediment, air; bioaccumulation; ecotoxicity, and other environmental endpoints. Each environmental

factor is designated by a ranking ranging from “very low” to “very high.” Where an alternatives assessment finds that an alternative chemical is acceptable, yet yields a higher ranking for one or more environmental factors, a “tradeoff” is said to occur. It is these tradeoff impacts (e.g., increased use non-biodegradable products offset by a reduction in human exposure to hazardous chemicals) that are likely to be significant under CEQA. A few examples of alternatives assessments performed under EPA’s DfE program are reviewed below, and copies of the studies are provided in Attachment B. The References cited in Attachment A to this letter contain many other examples for DTSC’s consideration.

Flame Retardants in Printed Circuit Boards—tetrabromobisphenol A (TBBPA) – An alternatives assessment was performed on exposure pathways and routes for 13 retardants used in printed circuit boards. The results of the assessment of seven formulations of flame-retardant products most likely to replace commercially available tetrabromobisphenol A (TBBPA) were presented. Six of the alternatives exhibited higher human health effects, aquatic toxicity, or environmental hazards than TBBPA. The alternatives assessments, to a degree, evaluated “other lifecycle considerations” for flame retardants, including environmental impacts occurring from raw material extraction, manufacturing, use, and end-of-life practices.

Nonylphenol Ethoxylates used in Surfactants – An alternatives assessment was performed for Nonylphenol Ethoxylates (NE). The alternatives assessment evaluated nine alternative compounds to NE with regard to the potential exposure related to environmental fate (persistence and degradates of concern), and aquatic toxicity (acute, chronic, and degradate aquatic toxicity). Eight of the nine alternative compounds were found to be acceptable alternatives to NE; however, six of the alternatives scored higher on one or more evaluated hazards.

Bisphenol A Alternatives in Thermal Paper-Draft Report – EPA prepared draft alternatives assessment on bisphenol A (BPA) used in thermal paper. As the alternatives assessment notes, BPA is a high production volume chemical (a monomer) used in manufacturing most polycarbonate plastics, the majority of epoxy resins, and other chemical products such as flame retardants. BPA has recently received public attention due to potential human exposure and its effects as an environmental pollutant as a reproductive, developmental, and systemic toxicant. It is commonly used in thermal paper applications, such as sales receipts, airline tickets, and cinema tickets.

Flexographic Ink – A comparative substitutes assessment was performed to evaluate the environmental impacts, health risks, performance, and cost of solvent-based inks, water-based inks, and ultraviolet-cured inks. The study concluded that “each of the ink systems studied had different advantages, as well as health and environmental concerns.” Therefore, replacing a COC in flexographic inks may result in an increased potential for significant environmental impacts under CEQA.

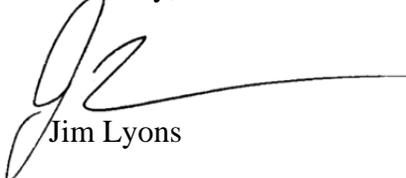
Wire and Cable Insulation and Jacketing – EPA conducted a life-cycle assessment of wire and cable insulation and jacketing for three classes of cable. Upstream material production, use, and electricity use—as well as recycling, disposal, end-of-life impacts—were evaluated. EPA found that, “Due to the presence of lead in the baseline

communication cables, the potential public non-cancer and aquatic ecotoxicity impact categories showed the greatest difference in environmental burden between the baseline and alternative cable constructions.” However, EPA noted that “Encouraging further recycling of chopped cable resin could potentially reduce the environmental burden of the baseline cable; however, there are other tradeoffs that would then need to be considered (e.g., the energy required for the cable chopping process).” These trade-off impacts may cause one or more CEQA thresholds of significance to be exceeded, thus resulting in a significant impact.

Desktop Computer Displays – EPA conducted a lifecycle assessment of desktop computer displays to determine the environmental impacts related to raw materials extraction/acquisition; material processing; product manufacture; product use, maintenance, and repair; and final disposition/end of life. The geographic coverage for each stage was evaluated and found to be “worldwide” for each materials acquisition, material processing, and manufacture, whereas “use” and “disposition” were assumed to occur only in the United States. The lifecycle assessment compared impacts from newer flat-panel (liquid crystal display) models to the older cathode ray tube (CRT) technology. Lifecycle impact indicator values were calculated with varying units per impact (e.g., megajoules for energy use and cubic meters for solid waste landfill space used). In 18 of 20 environmental categories, a lower-impact indicator was calculated for LCD monitors. However, for two environmental categories (water eutrophication and aquatic toxicity), the CRT monitors scored lower. This again indicates that a tradeoff impacts occurred, representing a potentially significant environmental impact under CEQA.

We thank you for your careful consideration of these comments.

Sincerely,



Jim Lyons

Attachments: References
Key Works Cited

ATTACHMENT A

REFERENCES

REFERENCES

1. Bay Area Air Quality Management District (BAAQMD), *California Environmental Quality Act, Air Quality Guidelines*, May 2012 (update), Available at URL: http://www.baaqmd.gov/~media/Files/Planning%20and%20Research/CEQA/BA_AQMD%20CEQA%20Guidelines_Final_May%202012.ashx?la=en, Accessed: September 13, 2012.
2. California Air Resources Board (CARB), Staff Report: Initial Statement of Reasons for the Proposed Amendments to the Control Measure for Perchloroethylene Dry Cleaning Operations and the Adoption of Requirements for Manufacturers and Distributors of Perchloroethylene, December 8, 2006, Available at URL: <http://www.arb.ca.gov/regact/2007/perc07/isor.pdf>, Accessed September 17, 2012.
3. *Davidon Homes et al, Plaintiffs and Appellants v. City of San Jose, Defendant and Respondent*, 54 Cal.App.4th 106, No. H0150182. California Court of Appeal, Sixth District. April 9, 1997, Available at URL: <http://ceres.ca.gov/ceqa/cases/1997/davidon.html>, Accessed: September 13, 2012.
4. Eliason, Pamela and Morse, Gregory, *Safer alternatives assessment: the Massachusetts process as a model for state governments*, Journal of Cleaner Production, 19 (2011) 517-526, May 12, 2010 (revised), Available at URL: <http://www.turi.org/content/download/6285/66171/file/jcp-volume19Issue5-517-526.pdf>, Accessed: September 13, 2012.
5. Keller, Arturo et al., *Health & Environmental Assessment of MTBE*, University of California, November 1998, Available at URL: <http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.22.2849>, Accessed September 19, 2012.
6. *Muzzy Ranch Co., Plaintiff and Appellant, v. Solano Airport Land Use Commission, Defendant and Respondent*, 41 Cal.4th 372; 160 P.3d 116; 60 Cal. Rptr. 3d 247; 2007 Cal. LEXIS 6508; 37 ELR 20150, Supreme Court of California, June 21, 2007, Filed. Available at URL: http://ceres.ca.gov/ceqa/cases/2007/Muzzy_Ranch_Co_v._Solano_County_Airport_Land_Use_Comm.htm, Accessed: September 13, 2012.
7. San Joaquin Valley Air Pollution Control District (SJVAPCD), *Guide for Assessing and Mitigating Air Quality Impacts*, Mobile Source/CEQA Section, January 10, 2001 (revision), Available at URL: <http://www.valleyair.org/transportation/CEQA%20Rules/GAMAQI%20Jan%202002%20Rev.pdf>, Accessed: September 13, 2012.

8. San Joaquin Valley Air Pollution Control District (SJVAPCD), *Draft - Guidance for Assessing and Mitigating Air Quality Impacts - 2012*, April 2012, Available at URL: http://www.valleyair.org/Workshops/postings/2012/4-25-12GAMAQI/draft_GAMAQI_2012_April11.pdf, Accessed: September 13, 2012.
9. Science Applications International Corporation (SAIC), *New Chemicals Environmental Technology Initiative, Automotive Refinishing Industry Isocyanides Profile*, EPA Contract No. 68-D4-0098, January 5, 2005, Available at URL: <http://www.epa.gov/dfe/pubs/auto/profile/cover-page.pdf>, Accessed: September 13, 2012.
10. Thabrew, Lanka; Wiek, Arnim; and Ries, Robert, *Environmental decision making in multi-stakeholder contexts: applicability of life cycle thinking in development planning and implementation*, *Journal of Cleaner Production*, 17 (2009) 67-76, March 19, 2008 (revised), Available at URL: http://asu.academia.edu/ArnimWiek/Papers/634099/Environmental_decision_making_in_multi-stakeholder_contexts_applicability_of_life_cycle_thinking_in_development_planning_and_implementation, Accessed: September 13, 2012.
11. USEPA, *Alternatives Assessment for Nonylphenol Ethoxylates*, Design for the Environment, Alternative Assessment Program, May 2012, Available at URL: <http://www.epa.gov/dfe/pubs/projects/npe/aa-for-NPEs-final-version5-3-12.pdf>, Accessed: September 13, 2012.
12. USEPA, *Flame Retardants in Printed Circuit Boards-Review Draft*, Design for the Environment, November 7, 2008, Available at URL: http://www.epa.gov/dfe/pubs/projects/pcb/full_report_pcb_flame_retardants_report_draft_11_10_08_to_e.pdf, Accessed September 17, 2012.
13. USEPA, *Flexographic Ink Options: A Cleaner Technologies Substitutes Assessment*, EPA 744-R-02-001A, Design for the Environment, February 2002, Available at URL: <http://www.epa.gov/dfe/pubs/flexo/ctsa/index.html>, Accessed: September 13, 2012.
14. USEPA, *Cleaner Technologies Substitutes Assessment: Lithographic Blanket Washes*, Design for the Environment, September 1997, Available at URL: <http://www.epa.gov/opptintr/dfe/pubs/lithography/ctsa/contents.html>, Accessed: September 13, 2012.
15. USEPA, *Draft Cleaner Technologies Substitutes Assessment (CTSA): Screen Reclamation*, EPA 744-94-005a, Design for the Environment, September 1994, Available at URL: <http://www.epa.gov/opptintr/dfe/pubs/screen/ctsa/index.html>, Accessed: September 13, 2012.
16. USEPA, *An Evaluation of Screen Reclamation Systems*, EPA 744-F-96-010, Design for the Environment, September 1996, Available at URL:

- <http://www.epa.gov/opptintr/dfe/pubs/screen/ctsa/scbook.pdf>, Accessed: September 13, 2012.
17. USEPA, *Wire and Cable Insulation and Jacketing: Life-Cycle Assessments for Selected Applications*, EPA 744-R-08-001, Design for the Environment, June 2008, Available at URL: http://www.epa.gov/dfe/pubs/wire-cable/wcp_lca_final_full_web.pdf, Accessed: September 13, 2012.
 18. USEPA, *Desktop Computer Displays A Life-Cycle Assessment*, EPA-744-R-004a, Design for the Environment, December 2001, Available at URL: <http://www.epa.gov/dfe/pubs/comp-dic/lca/index.htm>, Accessed: September 13, 2012.
 19. USEPA, *Solders in Electronics: A Life-Cycle Assessment*, EPA 744-R-05-001, Design for the Environment, August 2005, Available at URL: <http://www.epa.gov/dfe/pubs/solder/lca/lfs-lca-final.pdf>, Accessed: September 13, 2012.
 20. USEPA, *Printed Wiring Board Surface Finishes - Cleaner Technologies Substitutes Assessment*, Design for the Environment, Undated, Available at URL: <http://www.epa.gov/opptintr/dfe/pubs/pwb/ctsasurf/pwb-pub.htm>, Accessed: September 13, 2012.
 21. USEPA, *Implementing Cleaner Printed Wiring Board Technologies: Surface Finishes*, EPA 744-R-00-002, Design for the Environment, Printed Wiring Board Project, March 2000, Available at URL: http://www.epa.gov/dfe/pubs/pwb/pdf/sf_guide.pdf, Accessed: September 13, 2012.
 22. USEPA, *Printed Wiring Board Pollution Prevention and Control Technology: Analysis of Updated Survey Results*, Design for the Environment, Undated, Available at URL: <http://www.epa.gov/dfe/pubs/pwb/pdf/p2tech.pdf>, Accessed: September 13, 2012.
 23. USEPA, *Printed Wiring Board Cleaner Technologies Substitutes Assessment: Making Holes Conductive*, EPA 744-R-98-004a, Design for the Environment, Printed Wiring Board Project, August 1998, Available at URL: <http://www.epa.gov/dfe/pubs/pwb/ctsa/index.htm>, Accessed: September 13, 2012.
 24. USEPA, *Bisphenol A Alternatives in Thermal Paper-Draft Report*, Design for the Environment, July 2012, Available at URL: <http://www.epa.gov/dfe/pubs/projects/bpa/about.htm>, Accessed September 13, 2012.
 25. USEPA, *An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (DecaBDE)*, Design for the Environment, July 2012, Available at URL:

- http://www.epa.gov/dfepubs/projects/decaBDE/deca_fullreport.pdf, Accessed September 13, 2012.
26. USEPA, Design for the Environment Program Alternatives Assessment Criteria for Hazard Evaluation, Office of Pollution Prevention & Toxics, Version 2.0, August 2011, Available at URL: http://www.epa.gov/dfepubs/projects/decaBDE/deca_fullreport.pdf, Accessed: September 13, 2012.
27. Winnebeck, Kathryn H. *An abbreviated alternatives assessment process for product designers: a children's furniture manufacturing case study*, Journal of Cleaner Production, 19 (2011) 464-476, October 8, 2010 (revised), Available at URL: <http://www.turi.org/content/download/6291/66207/file/jcp-volume19Issue5-464-476.pdf>, Accessed September 13, 2012.



we wearSM safety

October 11, 2012

Deborah Raphael
Director
Department of Toxic Substances Control
1001 "I" Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: Safer Consumer Products Proposed Regulations; Public Notice and Comment Period; Office of Administrative Law Notice File Number: Z-2012-0717-04 (July 27, 2012)

Dear Director Raphael,

On behalf of the American Apparel & Footwear Association (AAFA), I am submitting the following comments in response to the request for public comments by the California Department of Toxic Substances Control (DTSC) on the Safer Consumer Products proposed regulations as identified in the file number referenced above.

AAFA is the national trade association representing apparel, footwear, and other sewn products companies, and their suppliers, which compete in the global market. Our membership consists of 380 American companies which represent one of the largest consumer segments in the United States. Of these companies, 59 are headquartered in California and represent thousands of jobs in the state. Most others, although not headquartered in California, retain employees in California in retail, distribution, design, and other roles.

Thank you for this opportunity to submit comments. As we have noted in previous comments, we wish to stress our association's support for the broad goals of the Safer Consumer Product Alternatives Regulations to develop tools to assist companies in their ongoing efforts to ensure they make and market safe consumer products, and to ensure consumers are aware of and have confidence in these efforts. However, AAFA and its members feel regulations can be effective only when they are transparent, predictable and clear. Our comments today will underline this notion while addressing specific segments of the proposed regulations.

§ 69501.4 – Chemical and Product Information

Section (a) (4) under this heading, allows for the Department to request manufacturers or importers to generate new information and provide it to the Department¹. Our concern with this requirement is the lack of specificity and details of what kind, how much, and how often this "new information" might be requested.

¹ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 18, (July 2012).

1601 North Kent Street
Suite 1200
Arlington, VA 22209

(703) 524-1864
(800) 520-2262
(703) 522-6741 fax
www.wewear.org

At some point, there must be a limit to how much information the Department can request for manufacturers and expect them to still be able to run a functioning operation.

§ 69502.2 – Chemicals of Concern Identification

This section of the regulations deals extensively with how COCs will be identified through these regulations². Specifically it outlines the mechanism by which the initial list of a certain number of COCs will be codified with the completion of the regulatory rulemaking process. In sum, chemicals that display a hazard trait and are on one of 22 separate lists of chemicals would automatically be included as COCs. In short, once the regulations are finalized, approximately 3,000 chemicals, according to documents released by DTSC, will be added as COCs. This is of concern to our industry for two reasons:

- 1) This change to the regulation has the effect of shortening the timeline for implementation of the regulation. Previous drafts of the regulation have called for the official process of generating a list of COCs to begin immediately upon completion of the regulations with an initial list of COCs due 6 months after the regulations have been finalized. This process significantly decreases the amount of time the business community would have to prepare compliance mechanisms for the regulations. It is important to note that for many industries, the apparel and footwear industry being one of them, supply chains can stretch as long as a full calendar year. In theory that means even if a company makes an immediate change to a product, it may be as long as year until the changes are reflected on the store shelf. In previous regulations like the Consumer Product Safety Improvement Act³ (CPSIA), short and unreasonable timelines for implementation have led to enormous confusion and costs throughout our industry before the Consumer Product Safety Commission (CPSC) ultimately had to step in to extend deadlines anyway. It is essential to the success of regulations that there is enough time built into them to allow companies to adequately prepare compliance mechanisms and avoid mass confusion in the various consumer product industries.
- 2) We are concerned with the idea of the initial list of COCs being automatically adopted upon the finalization of the regulations. In previous drafts of these regulations, DTSC would release an initial list of COCs that would be open for public comment upon finalization of the regulations. This would be the same process when any chemicals were under consideration for inclusion in the COC list. Although we do note the provision for a 45-day comment period for any revisions to the list as outlined in section § 69502.3 (c) (1)⁴, the current regulations do not allow for a dedicated public comment period for this initial list of over 3,000 chemicals.

As a final thought on the COCs, it would be very helpful if the list of COCs to be added immediately upon finalization of the current regulations, would be included in the regulations as a single appendix. Ideally, this list would be cross referenced with various other chemical management regulations such as REACH and TSCA, so industry would be able to see where there may be overlaps and redundancies. This would provide much needed clarity for companies and will also help companies which have comments or concerns to comment on the proposed COCs of which we are currently aware.

² Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Pages 21-24, (July 2012).

³ United States Consumer Product Safety Commission, The Consumer Product Safety Improvement Act of 2008: Public Law 110-314, (August 14, 2008).

⁴ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 24, (July 2012).

§ 69503.2 – Priority Products Prioritization Factors

We appreciate the approach DTSC has taken with regard to prioritizing products, rather than requiring every manufacturer with a COC in a product to perform an Alternatives Analysis (AA). However, we still have concerns with the product prioritization process.

The proposed regulations are fairly clear in what information will be used in determining whether a product should be included in the Priority Product (PP) list. We see that the priority determination will be based essentially on an evaluation of the COCs potential adverse impacts and exposures⁵. However, we are concerned that while the regulations are complete in what information will be used, it does not give insight into the process by which the information will be used. In this regard, the process lacks transparency and predictability, both of which are necessary for our industry to adequately prepare and understand the regulations.

With regard to measuring exposure as it relates to the product prioritization, we are pleased to see the department has included the concept of “intended use” of a product. We understand the department needs to look at total exposure potential when evaluating products. However, intended use should play a significant role in that evaluation process as the intended use is by and large the use for which the product will be utilized. Not giving weight to the intended use of a product when evaluating potential exposures has the unfortunate effect of punishing manufacturers for the consumers misusing their product, something over which the manufacturers have no control.

§ 69503.4 – Priority Products List

The promise of one or more public workshops to provide opportunity for oral comment on products being considered for the proposed PP list⁶ is a welcome step towards transparency in the process and we applaud DTSC for this initiative.

At the same time, the proposed regulations require the initial PP list be released for public comment by DTSC no more than 180 days after the regulations are finalized. Initial drafts of these regulations put that same deadline at 24 months after the finalization of the regulations. As was previously mentioned in these comments, allowing adequate time for implementation of the regulations is essential to avoid rampant confusion within the industry and ensure a smooth transition. This is especially true in relation to the PP list, as manufacturing a product contained on the PP list is the trigger to initiate a compliance process for manufacturers. Once a PP list is finalized, it automatically starts the clock on preliminary alternatives assessments. Therefore, it is essential there be adequate time built into this step of the process to allow companies time to put in place compliance mechanisms.

§ 69503.5 – Alternatives Analysis Threshold Exemption

While we are pleased that the department has included an Alternatives Analysis Threshold Exemption⁷, similar to what was previously known as a *de minimis* exemption, the concerns surrounding the practical use of the *de minimis* exemption remain in this new context.

As previous comments and past experience have shown, set threshold levels are not one-size-fits-all and attempting to approach it in this way undermines the outcome of such initiatives. Levels should be set on

⁵ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 25-27, (July 2012).

⁶ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 30, (July 2012).

⁷ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 31-32, (July 2012).

a case-by-case basis, as conducting evaluations based on potential COC exposure for each product and determining an individual threshold level based on that evaluation only strengthens the legitimacy of the levels and provides a sounder scientific basis for the levels.

Section 69503.5 (c) of the proposed regulations alludes to a process which is based on this notion of setting levels on an individual chemical basis⁸, but we ask that DTSC better define the process that will be used for setting levels. For example, section 69503.5 (e) allows DTSC to lower or raise a previously established AA threshold based on new, or newly considered, information⁹. Yet, there is no indication of what kind of new information would constitute a change in threshold levels.

§ 69503.6 – Alternatives Analysis Threshold Exemption Notifications

We strongly believe that the Alternatives Analysis Threshold Exemption notification process is unwarranted and undermines the reason behind having AA threshold levels in the regulations. Under the current regulations, a company must petition DTSC to accept that COCs in their product fall below the assigned threshold levels in order to avoid the AA process.¹⁰ The main purpose of the threshold level is to establish a concentration under which the chemical poses no appreciable risk. Having to undertake a tedious process of submitting the required notifications when COCs exist in amounts under the approved threshold level amounts to a burdensome requirement with no appreciable gain to consumer safety or chemical innovation.

Furthermore, standardized analytical testing methods for detecting COCs in certain products may not exist. In the absence of established testing methods, the 60-day time period allotted by DTSC for AA threshold exemption notification is generally insufficient time to develop testing methods and be able to notify DTSC of the results.

§ 69504 – Applicability and Petition Contents

The proposed regulations state a person may petition DTSC to add to or remove from the Chemicals of Concern list one or more chemicals, or to add the entirety of an existing chemicals list to the lists specified in section 69502.2 (a).¹¹ While we agree that private individuals should be able to petition the DTSC regarding COCs or PPs, the proposed regulations do not require the person be a California resident. As the regulations are in fact for the state of California, it seems odd that private citizens from outside the state would be able to petition for the DTSC to evaluate chemicals and products. We would recommend limiting the petitioning process to citizens of California and organizations with a presence in California.

§ 69504.1 – Merits Review of Petitions

We believe that the petitioning process described in Article 4 should provide an opportunity for all stakeholders, including industry, to comment and be notified of decisions. Earlier sections of the proposed regulations state additions to the COC list and PP list will be subject to a public comment period. This being established, this section of the regulations is unclear as to whether chemicals and products that are reviewed and accepted by DTSC will be included outright on the lists, or if they will be put on proposed lists which are subsequently open to public comment. We would strongly urge DTSC to

⁸ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 31, (July 2012).

⁹ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 32, (July 2012).

¹⁰ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 32 -33, (July 2012).

¹¹ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 34, (July 2012).

embrace the latter of the two options. If chemicals and products whose petitions are accepted by DTSC are placed on the COC and PP lists outright, it completely excludes industry and other stakeholders from the opportunity to comment on the regulations.

§ 69505.1 – Alternatives Analysis: General Provisions, § 69505.3 – Alternatives Analysis: First Stage, and § 69505.4 – Alternatives Analysis: Second Stage

We have several concerns related to the two-stage AA procedures outlined in Article 5 of the proposed regulations.¹² The basic purpose behind the AA seems to be to provide manufacturers a pathway toward reformulation when a PP contains a priority chemical. We appreciate the need to outline a regimented process and the fact that DTSC will be providing further guidance on completing AAs prior to the first PP list being published, however the process that has been created will be extremely expensive for companies who need to complete an AA. One approach to alleviate that burden would be to cut down on the number of AAs that must be completed. We have three suggestions to accomplish this goal.

1. Currently the regulations require companies to submit an AA if they are responsible for a product which is named to the final PP list, even if all the COCs from the priority product are removed. A simpler approach would be to enable manufacturers who choose to remove a chemical to simply send a chemical removal notification to DTSC which includes the effective date of the change. Such a system would also give DTSC a simpler workload so they can easily understand and trace industry reactions to the publication of various lists.
2. Another option to reduce the amount of AAs being conducted is to allow companies to collaborate. AAs for assembled products center on the components of the product which contain the COCs. If a number of companies within the industry share common components, for example zippers, it would greatly reduce the number of AAs to be completed, if the companies could submit a joint AA. The proposed regulations make it difficult to determine whether or not this kind of cooperation would be acceptable. We ask that the process be made clearer going forward.
3. Finally, it would be helpful if the use of third party chemical management certifications could be incorporated into the AA process. A number of companies already use these certifications to help with various chemical management regulations. A clear explanation of how these certifications may be used in the regulations may not help reduce the number of AAs which must be conducted, but it would certainly make the process much easier and less resource intensive.

We appreciate that the regulations no longer require the use of a third party to do the AAs, as was the case in previous regulations. However, the regulations still require the use of a certified assessor for all AAs completed two years after the effective date of the regulations be performed by a certified assessor as outlined in Article 8.¹³ This is an unnecessary expense for our members to incur. Regardless of whether they hire an outside certified assessor, which amounts to a third party assessor, or if they have one of their staff certified to do the AAs, it represents a superfluous and burdensome expense.

Most of the companies in our industry have very qualified personnel already in their employ and may be more than capable already to perform the AA. The argument gains credence, especially when one considers that ultimately it is the responsible entity that is responsible for the content of the AA and complying with the regulations, not the certified assessor. Forcing companies to use a certified assessor needlessly cedes power from those responsible for compliance to those with no stake in it. Companies are ultimately responsible for their AAs and compliance. Therefore, it should be left up to each individual

¹² Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 36-52, (July 2012).

¹³ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 37 and 65-66, (July 2012).

company to decide whether or not it is necessary to enlist an outside assessor or to have their own personnel certified in order comply with the regulations.

§ 69505.2 – Analysis of Priority Products and Alternatives

We are appreciative of DTSC for showing flexibility and an openness to cooperate with the inclusion of section 69505.2 (c) which allows companies to utilize an AA process which differs from the process previously outlined within the regulations.¹⁴ This type of flexibility allows companies to streamline some of the compliance requirements with internal procedures they may already have in place. It reduces the burden, and could prevent companies from being forced to recreate the wheel internally, so-to-speak.

§ 69507.6 – Department Procedures for Requests for Review

The regulations are clear on which of the decisions from DTSC qualify for the formal dispute resolution procedure and the informal dispute resolution procedure. Our main concern lies with the formal dispute resolution procedure. Under no circumstances do we support a procedure in which DTSC can deny a review of a dispute.¹⁵ This is the main protection built into the regulations for industry. The allowance for DTSC to simply deny a request undermines the entire principle of the safeguard. We request that a more robust system be put in place that does not allow DTSC to deny requests for dispute resolution.

§ 69508 – Qualifications and Certification for Assessors and § 69508.1 – Qualifications for Accreditation Bodies

We have already outlined our serious misgivings with the requirement of a certified assessor for AAs and the corresponding accreditation program for organizations. However, if such a program must exist, we want to stress that it should not preclude those organizations with which industry already has relationships. It is common for our members to already use testing labs for various services including product safety compliance. These organizations often are already equipped with their own labs to do the testing required under this regulation. It would seem that they are a natural fit to serve as accrediting bodies so their employees can become certified and conduct the AA's for their already existing clientele.

§ 69510 – Assertion of a Claim of Trade Secret Protection

We remain deeply concerned about the inadequate provisions laid out in these regulations to protect trade secret information. We acknowledge there are several provisions that permit companies to claim information is of a sensitive nature and must be kept confidential. Yet those same provisions also require the public filing of redacted information, even when the non-redacted portions would end up divulging confidential information through context. Moreover, making the redacted copy available at the discretion of DTSC is inconsistent with Sections 69501.5 (b) (6) of these regulations.

The trade secret provisions in Article 10¹⁶ contain troubling requirements for companies to justify why they believe information is confidential. For example, filing a request for trade secret protection requires companies to speculate as to how much the information would be worth to competitors, and how readily competitors would be able to replicate the information on their own. It would be very difficult for companies to attempt to quantify this type of information for themselves, let alone a competitor who may have very different internal mechanisms and cost structures. Therefore, we feel the process by which

¹⁴ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 39-40, (July 2012).

¹⁵ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 64-65, (July 2012).

¹⁶ Department of Toxic Substances Control, Safer Consumer Products Proposed Regulations: R-2011-02, Page 75-77, (July 2012).

companies apply for trade secret protection should be reexamined with an eye for keeping information requirements within the realm of what can be reasonably expected for companies to know.

Some of the questions in the trade secret protection provision appear to attempt to establish a dollar figure for the information. This is an ultimately unwieldy strategy, as the value of this information is often in name recognition and product reputation in addition to dollar amounts. Furthermore, information that can be quantified materially is at serious risk of being taken out of context. For example if a dollar amount is assigned to a piece of information, how is that assigned worth? Companies vary in size and revenue structures, and information valued at X dollars can be worth drastically different things to different companies. Nowhere in Article 10, which deals with trade secret information, is there any attempt to capture information which would put a dollar value into context. It is our recommendation that questions of this nature be completely excluded from the trade secret protection process.

General Comments

Our industry's main concern within this field is the growing patchwork quilt of chemical management regulations we are seeing across the United States. We understand and fully support a state's prerogative to enact legislation it deems will protect its citizens in absence of federal action. However, we would be remiss if we did not make regulators aware of the difficult position in which this places business. It is our hope that regulators continue to look at different ways to work with other states to streamline the regulatory requirements for products as much as possible.

Thank you for your time and consideration in this matter. Please do not hesitate to contact AAFA if we can be of any help to you. Please feel free to contact me or Marie D'Avignon of my staff at 703-797-9038 or by e-mail at mdavignon@wewear.org if you have any questions or would like additional information.

Sincerely,

A handwritten signature in black ink that reads "Kevin M. Burke". The signature is written in a cursive, flowing style.

Kevin M. Burke
President & CEO



October 10, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Safer Consumer Products Proposed Regulations, R-2011-02

Dear Ms. Von Burg:

The American Cancer Society Cancer Action Network (ACS CAN) California strongly supports the Safer Consumer Product Alternatives Regulations proposed by the Department of Toxic Substances Control (Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04). As an organization dedicated to fighting cancer, ACS CAN promotes and supports policy decisions that are likely to result in decreased cancer incidence in the population. We feel that these regulations, if adopted and implemented as written, will be a valuable first step in assessing the safety of consumer products and encouraging creation of new products formulated without chemicals known to cause cancer.

Manufacturing and distributing consumer products that contain known chemical carcinogens place both workers and consumers at increased risk of getting cancer. This is unacceptable when products having similar functionality but created using safer ingredients are available, or the technology to create such products is available. We encourage the Department to work closely with public health organizations in both governmental and non-governmental organizations to identify and target products containing chemical carcinogens for reformulation, marketing restrictions, and eventual removal from commerce.

Thank you for the opportunity to comment on these landmark regulations. We will continue to monitor implementation of these regulations. We look forward to working with the Department to promote better public understanding of the risks posed by certain chemicals in our environment and the development of strategies for minimizing associated human health impacts from exposure to these chemicals.

ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. ACS CAN supports evidence-based policy and legislative solutions designed

California Office

980 9th Street, Suite 2200 • Sacramento, CA 95814-2742
t) 916.448.0500 • f) 916.447.6931



to eliminate cancer as a major health problem. For more information, visit www.acscan.org.

If you have questions or we can provide additional information, please contact Sharen Muraoka at sharen.muraoka@cancer.org or 916-504-2474. Thank you for your time and your consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'J.K. Knox', is positioned above the printed name.

James K. Knox
Vice President, Advocacy

California Office

980 9th Street, Suite 2200 • Sacramento, CA 95814-2742

t) 916.448.0500 • f) 916.447.6931



VIA ELECTRONIC MAIL

October 11, 2012

Krycia Von Burg, Regulations Coordinator
Regulations Section
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
E-mail: gcregs@dtsc.ca.gov

RE: Comments on proposed Safer Consumer Product Regulation (R-2011-02) July 27, 2012

Dear Ms. Von Burg:

The American Chemistry Council (ACC)¹ respectfully submits the attached comments and supplemental materials relative to the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Regulation, July 27, 2012 (hereafter referred to as the "proposed regulation").

Our comments highlight our views and questions on issues that we believe require substantial consideration and clarification before the rule is promulgated. ACC has actively and constructively engaged DTSC on the Green Chemistry Initiative for over five years. ACC continues to be an active member of the Green Chemistry Alliance (GCA), and we and our GCA partners have invested considerable effort to provide our best thinking about an approach that meets the requirements of the authorizing statute and fosters a rational, predictable, science-based regulatory environment. We are disappointed that the proposed regulations do not reflect a more objective framework and believe the proposed regulation falls short of achieving the critical tests of clarity, necessity, authority, consistency and nonduplication with California law.

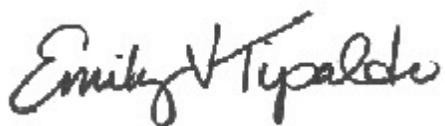
¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$720 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.



Furthermore, ACC shares the concerns of Senator Michael Rubio regarding the poor economic analysis provided by DTSC. The Economic and Fiscal Impact Statement Form 399, for example, fails to give any indication of potential costs to businesses throughout California, the total number of businesses created, and the number of businesses that will be eliminated. For a regulatory program of this magnitude a better understanding of the economic impact is necessary.

In conclusion, ACC appreciates the degree to which DTSC has engaged all stakeholders throughout the regulation development process. However, we are extremely disappointed that DTSC has ignored many of the substantive comments and suggestions we and our GCA partners have provided. It is imperative that DTSC rectify the issues of clarity, necessity, consistency, authority, and non-duplication, for the regulation will have consequences to businesses and their employees within and well beyond the borders of California.

Sincerely,



Emily V. Tipaldo
Manager, Regulatory and Technical Affairs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA (MRodriguez@calepa.ca.gov)
Miriam Ingenito, Deputy Secretary, CalEPA (mingenito@calepa.ca.gov)
Kristin Stauffacher, Assistant Secretary, CalEPA (kstauffacher@calepa.ca.gov)
Nancy McFadden, Cabinet Secretary, Office of the Governor
(Nancy.McFadden@gov.ca.gov)
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
(Mike.Rossi@gov.ca.gov)
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
(Cliff.Rechtschaffen@gov.ca.gov)
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor
(Martha.Gusman-Aceves@gov.ca.gov)
James Jones, Acting Assistant Administrator, US EPA (Jones.Jim@Epa.gov)



**Comments of the American Chemistry Council
on the
Proposed Safer Consumer Product Regulation
(July 27, 2012 (R-2011-02))**

October 11, 2012

Emily Tipaldo
Manager
Regulatory and Technical Affairs

American Chemistry Council
700 2nd Street, NE
Washington, D.C. 20002

Table of Contents

Executive Summary.....i

I. General Comments.....1

II. DTSC Should Conduct a More Robust Economic Assessment.....4

III. A Review of the Proposed Regulation Against Standards Established by of Office of Administrative Law Standards Establishes a Number of Shortcomings.....5

 A. Necessity (Government Code §11349(a)).....5

 B. Authority (Government Code §11349(b)).....9

 C. Clarity (Government Code §11349(c)).....14

 D. Consistency (Government Code §11349(d)).....25

 E. Nonduplication (Government Code §11349(f)).....25

Executive Summary

The American Chemistry Council (ACC) appreciates the opportunity to comment on the California Department of Toxic Substances Control's (DTSC) proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code, to promote safer consumer products.

Despite industry's considerable efforts over the last five years to suggest meaningful, practical and legally defensible regulatory alternatives to DTSC, the current proposal demonstrates limited progress in critical areas of the regulation. Although minor changes are reflected, the regulatory Green Chemistry program must have a stronger objective and scientific foundation in order to credibly inform choices made by consumers and other participants in the value chain. In ACC's view, the regulations require considerable additional work before they are made final.

ACC is particularly concerned that the complexity, scope and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to chemicals that pose risks of harm and promoting innovation. At best the proposed regulation will produce a marginal improvement in human health and environmental safety, but at great expense and lost opportunities for businesses nationwide. Although DTSC has estimated that some 1,200 substances will be covered by the regulation, ACC estimates that the regulation would affect at least 4,000, if not more. Among the significant implementation costs is the need for extensive government resources, at a time when the State is already facing critical resource.¹

ACC is also concerned that the regulation creates the real prospect of consumer confusion and unwarranted alarm as more than a thousand of the most commercially important substances are designated as subjects of the state's "concern," based only on a loose assessment of hazard characteristics gleaned from lists compiled by other (non-State) entities. In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer products. More to the point, consumer apprehension will certainly lead to deselection by the value chain, resulting in product performance which fails to meet consumer expectations and needs. ACC believes that DTSC has not fully assessed the potential for the regulation to result in sports equipment that is less protective, building products that are less weather-resistant or energy efficient, and food packaging that provides shorter shelf life, to name just a few.

Indicative of the ACC's general concern with the proposed regulation is that DTSC's economic analysis fails to provide any meaningful insight into whether the proposal is an efficient and effective means of implementing the relevant Code provisions in the least burdensome manner, as required under California law.

ACC strongly recommends DTSC consider a tailored program that is practical, meets the goals of AB 1879, and is focused on substances in consumer products identified as a potential risk for

¹ The California State Budget 2012-2013 indicates that the State debt is estimated to be \$16 billion, coupled with a \$3.5 billion tax (revenue) shortfall in the current fiscal year. *See* <http://www.ebudget.ca.gov/pdf/Revised/BudgetSummary/FullBudgetSummary.pdf>.

human health and the environment based on a scientific assessment of hazard and exposure. We believe that a more direct approach to the implementing regulation would address the practical problems raised by the scope and complexity of the proposed rule. In summary a properly scaled program would:

- Identify a relatively small, initial set of chemical substances that meet specific criteria.
- Identify the consumer product uses of those substances that are not otherwise regulated by federal or state law, or that have exposure and use patterns that may pose risks.
- Prioritize those substances for additional evaluation and review. ACC has developed a chemical prioritization tool that can be adapted to DTSC's use, with appropriate modifications addressing consumer product uses. A copy of the prioritization approach is attached to these comments.
- Identify and prioritize future "batches" of chemical substances using the same approach.
- Request manufacturers and importers of priority products to submit data and information on the chemical substance and its use in the identified consumer product.
- Require alternative assessments only when the chemical of concern in the priority product poses a substantial risk of harm.

Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

The following areas are of particular concern to ACC and its members. Each area is discussed in Section II in the context of the standards for necessity, authority, clarity, consistency and non-duplication established by the California Office of Administrative Law.

- Identification and Prioritization of Chemicals of Concern
- Priority Product Prioritization Process
- Trade Secrets
- Public Participation and Transparency
- Alternatives Analysis Exemption Threshold

ACC's comments include constructive recommendations for improving the proposed regulation, minimizing its potential negative impacts, and realizing the stated objectives of the underlying statute. We look forward to continuing our work with DTSC toward these mutual goals.

I. General Comments

A. Practicality and Efficient Implementation Should Guide the Regulation

The 78 pages constituting the proposed regulation provide a complex approach to a problem that should be amenable to relatively simple solutions. In an apparent attempt to ensure that the regulation is comprehensive, DTSC has cast a wide net that implicates nearly every segment of the national economy. ACC firmly believes that a more tailored approach is warranted given the concerns raised by the proposed regulation.

ACC supports DTSC's primary objective to protect human health and the environment from harmful exposures to chemical substances. Chemistry touches 96% of all manufactured goods, including the consumer products which are the target of the regulation. The non-confidential federal Toxic Substances Control Act (TSCA) Inventory includes some 85,000 substances (some 7,000 of which are in general U.S. commerce in substantial amounts). Nearly every one of those substances is potentially subject to listing as a "chemical of concern" under this proposed regulation, despite the fact that many are used safely every day, in thousands of applications.

1. Products otherwise regulated by federal law should be excluded.

Until DTSC makes an affirmative determination as to the relationship between the proposed regulation and regulations under other federal or state laws, the regulation applies to products regulated under other comprehensive systems, including the Federal Food, Drug and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Consumer Product Safety Act (CPSA), the Federal Hazardous Substances Act (FHSA), and TSCA.² Even food contact packaging – otherwise regulated nationally by the Food and Drug Administration – is subject to the proposed regulation.

The proposed regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans and operations to be made publicly available. ACC is particularly concerned that DTSC will not have the staff or financial resources to properly process and manage the volume of information that will be reported under the proposal. Most importantly, DTSC needs to be mindful about how the information related to chemicals used in consumer products is communicated to the public. The proposed regulation will have little value if it simply creates unwarranted consumer anxiety about chemicals (e.g., suggesting a risk of harm where none exists), or imposes regulatory requirements that have marginal impact on health and environmental protection beyond that provided by existing labeling, warning, and use restrictions.

2. DTSC must assure that reliable information is the basis for listing chemicals and products.

The broad scope and complexity of the regulation is exacerbated by an approach that relies on loosely defined "reliable information" as the basis for listing a chemical of concern. It is a general principle of hazard assessment that all available data must be considered and the totality

² See attached "List of Federal Statutes Regulating Chemicals".

of relevant and reliable information integrated in order to arrive at a scientifically defensible decision regarding chemical hazard. Since, in many cases, dozens of toxicological studies will be available for review on any given chemical, the only valid scientific approach is to consider the weight-of-the-evidence as part of the standard protocol. A scientifically sound weight of the evidence analysis involves evaluating each study for data quality and reliability and then integrating data from all relevant studies.

Unfortunately, the proposed regulation does not adopt a weight-of-the-evidence approach. Without that approach a single study, regardless of its quality (and irrespective of other available relevant data), could be used to conclude that a chemical possesses “suggestive evidence” of a specific hazard.³ The framework that DTSC and the Office of Environmental Health Hazard Assessment (“OEHHA”) should employ must include a transparent, scientifically-based evaluation of the overall weight of evidence to establish a *causal* relationship between an outcome of concern and exposure to a substance. We urge DTSC to include a weight-of-the-evidence approach in the regulation and articulate it will be used in decision-making, particularly with regard to prioritizing chemicals of concern and products.

3. Aggregate and cumulative risk evaluation imposes considerable burden.

DTSC proposes to consider aggregate and cumulative effects as part of the chemical identification and the priority product prioritization process. It is unclear when, how often and through what process DTSC will evaluate aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or both. ACC is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks (the total exposure to a specific chemical from all different sources and routes) requires considerable data and information that manufacturers of individual products typically do not have and may be difficult to readily obtain. Aggregate assessments should only be required on a case-by-case basis for chemicals that meet certain criteria (e.g., cases that present a very narrow margin of safety).

The assessment of cumulative effects or risks (the common toxic effect from concurrent exposure to risks from other chemical and non-chemical sources) poses even greater challenges. Cumulative risk assessment is far from settled science. As with aggregate effects, scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. For example, the most recent cumulative risk assessment recommendations of the U.S. National Research Council expert panel contrast with EPA’s current practices and those of the World Health Organization’s International Programme on Chemical Safety.⁴ In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

³ OEHHA Green Chemistry Hazard Traits for California’s Toxics Information Clearinghouse (October 7, 2011), §64206.6(b).

⁴ Compare, e.g., Phthalates and Cumulative Risk Assessment: The Task Ahead (2008), Committee on the Health Risks of Phthalates, National Research Council, The National Academies Press, Washington, D.C. with Risk Assessment Of Combined Exposures To Multiple Chemicals: A Who/IPCS Framework (2009). World Health Organization, International Programme on Chemical Safety (IPCS), Harmonization Project DRAFT Document for

It is not clear if DTSC intends to follow the practice of the federal Environmental Protection Agency in assessing the cumulative effects of certain pesticides, which is to conform to the state of the science. The level of knowledge required to conduct a cumulative assessment, even for a group of chemicals that share a common mechanism of toxicity, is orders of magnitude over and above that required to conduct an aggregate assessment, and is not practical for the vast majority of chemical substances, mixtures and uses.

In the 16 years since the federal Food Quality Protection Act (FQPA) was enacted, the science has proven to be so difficult, even for groups of chemicals having a common mechanism of toxicity, that EPA has only been able to conduct cumulative risk assessments for 4 groups of pesticide active ingredients. For all practical purposes, DTSC would require an encyclopedia of all substances arrayed by the adverse effects they are capable of producing and the dose levels associated with such effects, both natural substances and synthetic agents, including consumer products, industrial chemicals and pharmaceuticals and understand the temporal, demographic and geographic exposures to each of these. Beyond that, DTSC would also need to know the background exposure for the chemical being evaluated.

Complicating this analysis is that DTSC would have to go through the same exercise for any additional priority product, add that exposure to the evaluation, resulting in a virtually infinite analysis loop.

Simply, ACC believes there is no practical way to incorporate cumulative assessment as a routine component of the Safer Consumer Product regulation. The burden of analysis on DTSC and the industry would be very high, and will divert scarce resources from managing important risks.

4. DTSC's approach to threshold concentrations is focused on eliminating exposures, rather than minimizing them.

DTSC's proposed regulation and the Initial Statement of Reason (ISOR) indicate that DTSC will defer to the "minimum detectable concentration" level for the "Chemical of Concern" in the product.⁵ ACC is concerned that reliance on the limit of detection focuses DTSC's efforts on chemical elimination rather than safe use. This concern is heightened by DTSC's proposed reliance on regulatory responses that provide the greatest level of "inherent protection." This approach stands in sharp contrast to the statutory requirement that DTSC's regulations must "establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine ***how best to limit exposure or to reduce the level of hazard posed by a chemical*** of concern, in accordance with the review process specified in Section 25252.5."⁶

Public and Peer Review, available at

<http://www.who.int/ipcs/methods/harmonization/areas/aggregate/en/index.html>.

⁵ Initial Statement of Reasons: Safer Consumer Products, R-2011-02, <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>, p. 104, §69503.5, p. 107, §69503.5(c)(2)(A).

⁶ California Health and Safety Code Section 25253 (emphasis added).

A minimum detectable concentration cannot function as an exemption threshold, nor can it be used to document incremental improvement in a particular product. The ISOR importantly notes that “at very low concentrations, it is impossible for analytical instruments to distinguish the difference between signals from analytes and signals created by the instrument.”⁷ In practical terms, the minimum *detectable* concentration is essentially zero. It is unclear how a manufacturer or importer covered by the regulation would use a minimum detectable concentration to demonstrate reductions in chemicals of concern?

5. DTSC should clarify its authority to impose regulatory restrictions on substances and products.

The proposed regulation also raises an interesting question about DTSC’s grant of authority to impose regulatory restrictions. DTSC should address this issue before making the regulation final. The underlying statute permits DTSC to adopt regulations to establish criteria for identifying and prioritizing chemicals of concern and to develop criteria to evaluate them and their alternatives in consumer products (Health and Safety Code §§25252-25253(a)(1)). Additionally, the statute authorizes DTSC to “specify the range of regulatory response that the department may take following the completion of the alternatives analysis” (HSC §25253(b)). ACC encourages DTSC to clarify how the apparent authority to impose product information disclosure requirements, end-of-life management schemes, product bans, and a range of other potential regulatory responses will be exercised.

II. DTSC Should Conduct a More Robust Economic Assessment

DTSC estimates that it will be able to implement the entirety of the program within the Administration’s proposed 2012 budget, applying 39 full-time employees and a \$6 million budget.⁸ ACC believes DTSC has significantly underestimated the costs of the program, and strongly recommends that the Agency conduct a more robust economic assessment of the regulation.

The Chemical Risk Review and Reduction program at the federal EPA has been estimated to cost \$40-\$45 million (not including new chemicals). Even if California managed to operate at half of EPA’s budget, it would still need at least three times more than the \$6 million budgeted for the regulation. Based on knowledge of EPA’s processes and costs and an independent assessment of the potential costs to DTSC, annual implementation costs are estimated to range from about \$9 million to \$27.2 million in the first six years, depending on the scope of the Safer Consumer Product program.⁹

California’s chemical industry is far more complex than what is depicted in DTSC’s economic analysis of the proposed regulation. There are approximately 600 chemicals that are produced in

⁷ Id.

⁸ Attachment 3 to the Economic and Fiscal Impact Statement (Std. Form 399) Safer Consumer Product Regulations.

⁹ For further projected costs to both the state of California as well as the regulated communities, please see the attached reports developed by ICF under contract for ACC: “Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Alternatives Regulations under CCR 22,” July 26, 2012, and, “Addendum: Industry Costs.”

the state of California.¹⁰ The value of the chemical shipments is almost \$46 billion and the California chemical industry exports \$12.5 billion worth of chemicals throughout the world. The business of chemistry directly employs 74,000 people and indirectly contributes 239,000 jobs in California. For every chemistry industry job in California, 4.2 jobs are created downstream within the state. Together these jobs generate \$23 billion in earnings which then also generate state and federal revenues through taxes. State and federal income taxes on these industries' payrolls support government programs for the residents of California.

These indicators provide a starting point for a more robust economic analysis of the regulation that assesses the impact of a regulation on the chemical industry and on California's economy as a whole. Dr. Kahn's analysis for the State¹¹ is not sufficient. The analysis provides no quantitative estimate of costs or benefits, and takes no account of the chemical industry and the downstream impacts in the State.

Similarly, the proposed regulation neglects to mention small businesses or acknowledge potential compliance challenges that small and medium-sized businesses will face as a result of the proposed regulation. While ACC believes that all responsible parties should be held to the same standards, DTSC should consider compliance challenges, particularly costs, for small and medium-sized businesses. We urge DTSC to assess the potential impacts of the regulation on small and medium-sized enterprises.

III. A Review of the Proposed Regulation Against Standards Established by the Office of Administrative Law Establishes a Number of Shortcomings.

A. Necessity (Government Code §11349(a))

1. DTSC should include a weight-of-the-evidence assessment process.

To build overall confidence in the Green Chemistry Program, DTSC must ensure that the regulation adopts a rigorous, science-based approach, in concert with state, federal and international best practices. The reliance on rigorous science must be evident in the selection of chemicals of concern and priority products, in identifying a threshold for and process of alternatives assessment, and in determining what regulatory responses the Agency will take.

The proposed regulations raise significant concerns that the Department will oversee a program that simply accommodates inadequate, unreliable or low quality science. If this occurs, resources will not be directed to the most compelling chemical hazards, but to controversies generated by unreliable studies and amplified by special interest groups and a media that thrives on novel health scares.

Our concerns start with inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure," which do not require a means to assess

¹⁰ IHS™ Directory of Chemical Producers®, Englewood Colorado.

¹¹ Attachment 2, "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products," Matthew E. Kahn, March 2012.

the quality of information, but focus on whether the information is in the public domain. This problem is exacerbated by an absence of emphasis on a weight of evidence evaluation of information, as well as the dependence on the “most protective” study independent of its actual quality and reliability. Leading to an even more unscientific position is the Department’s position that when all other factors are equal, decisions will not necessarily be driven by conclusions from the most relevant and highest quality studies, but rather from the “greater amount of information.”

In evaluating information to make decisions and substantiate their conclusions about “the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts,” DTSC should be guided by the following principles:

- DTSC’s decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for the public to have sufficient confidence in DTSC’s use for health and environmental regulatory decision making. If the process does not meet these benchmarks, there is no assurance that the program will in fact benefit consumers.
- All evaluations must rely on the best available scientific information regarding possible hazards of substances, and must employ consistent, objective methods and models to derive realistic determinations of risks at environmentally relevant levels of exposure.
- Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.
- All evaluations must be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.
- Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks. The characterization should provide a full picture of what is known and what has been inferred, and should also present results based on alternative plausible assumptions.
- Assessments must provide full disclosure of key information. When assumptions (or policy preferences) are used in lieu of scientific data, the assumptions (and policy preferences) must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

ACC believes it is necessary for DTSC to incorporate these principles into Article 1 of the regulations to provide the overall theme and foundation for science-based implementation.

In Sections 69502.2(b)(3) 69503.2(a)(2) of the proposed regulation, it is not clear how or whether a weight-of-the-evidence assessment will be applied when a chemical or a product is being evaluated. It is also not clear whether the Department simply intends to assign a higher priority to the chemical substance that simply has a greater amount of information. DTSC must clarify its approach to weight-of-the-evidence assessments.

2. DTSC must assure it has the resources to manage data and information.

DTSC is proposing to provide an unprecedented (and arguably unnecessary) level of information about products, chemicals, and manufacturer's business plans to the public, public interest groups, competitors, and retailers. Overall, ACC is concerned that DTSC will not have the resources to properly manage the volume of information that will be reported under the existing proposal. DTSC should also be mindful of how the various forms of information are communicated to the public. Specifically, ACC recommends that DTSC exercise a concerted and purposeful communication effort not to create unwarranted consumer or public anxiety regarding the chemicals on the initial list.

ACC encourages DTSC to confer with Washington State and Maine regarding the data collection challenges faced during implementation of the Children's Safe Product Reporting Rule, and the Regulation of Chemical Use in Children's Products, respectively. What will be clear is that to maximize the efficiency and utility of data and its collection, the regulatory need for specific data should be the driver for regulatory requirement for submission, not perceived gaps in the data DTSC possesses.

3. Information certification requirements are not necessary.

ACC is troubled by the proposed requirement to have all information submitted to DTSC signed and certified not only the responsible individual in charge, but also by the owner or an officer of the company, or an authorized representative (§69501.3(a)). While the requirement will certainly draw the attention of upper management, as DTSC no doubt intends, it is also unreasonable and unnecessary. DTSC proposes to review each submission, from Alternatives Analysis Exemption Notifications to Final Alternatives Assessment (AA) Reports. The additional certification requirement is superfluous in the situation where an AA is conducted by a certified assessor, according to DTSC's certification and accreditation process.

4. Key statutory prioritization factors must be included.

As proposed, the regulation identifies a vague, subjective process by which DTSC will prioritize and establish a list of Priority Products. While ACC appreciates that the Priority Products list is apparently intended to be risk-based, as the regulation requires some consideration of exposure and the potential for harm, we also believe DTSC has not adequately represented the three criteria noted in the underlying statute (§69503.2(b)):

- 1) The volume of the chemical in commerce in this state.
- 2) The potential for exposure to the chemical in a consumer product.
- 3) Potential effects on sensitive subpopulations, including infants and children.

DTSC should, at a minimum, include these three items as the "Key Prioritization Criteria."

5. An analytical method for establishment of an alternatives analysis threshold is not needed.

DTSC will require an analytical method for the establishment of each Alternatives Analysis Threshold (“AAT”). §69503.5(c)(2)(A). It is not clear why the Agency will require this step for substances that already have an established *de minimis* threshold. At a minimum, DTSC should make a clear statement of the value derived from this requirement and the regulatory necessity for the mandate.

6. Additional alternatives assessment exemptions are required.

The proposed regulation indicates where alternatives assessments are not necessary or required. §69505.1(b)(1) – (3). ACC believes the proposed exemptions are consistent with the authorizing statute and recommends that DTSC identify two additional instances where alternatives assessments are unnecessary:

- An alternatives assessment is not required if the responsible entity determines that the Chemical of Concern is not necessary for the product to continue to meet function, performance, technical feasibility, and legal requirements and certifies within 60 days of notifying the Department of its determination, its intent to stop using the Chemical of Concern in the Priority Product and will not use a substitute chemical in place of the Chemical(s) of Concern that is the basis for the priority product designation. The manufacturer must confirm that it has begun the process of removing the Chemical(s) of Concern that is the basis for the priority product determination no later than 120 days after the date the manufacturer notified the Department of its intent; and
- An alternatives analysis is not required if the responsible entity replaces the COC that is the basis for the Priority Product determination with a substitute chemical that is not on the COC list, and thus does not exhibit the toxicity trait(s) that caused the Chemical of Concern to be on the Chemical of Concern List.

7. Sensitive information should not be required in alternatives analysis reports

ACC cautions against requiring information in §69505.5 Alternatives Analysis Reports that unnecessarily results in the submission of large quantities of potentially sensitive personal and business information that is not particularly germane to the core of alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program. *See* §69505.5(d).

8. Accreditation bodies and certified assessors are not necessary to achieve the object and purpose of the regulation.

ACC questions the need certification of accreditation bodies and certified assessors. The underlying statute neither explicitly nor implicitly mentions such a regulatory construct. Other chemical management programs across the globe have given rise to a network of sophisticated reputable firms and academic institutions capable of performing such work, thus eliminating the

need for certification and accreditation. The proposed regulation will create a large, bureaucratic process that is not necessary to ensure the conduct of rigorous alternatives assessments or to implement the statute.

9. The selection principles for regulatory responses should weigh multiple factors.

ACC urges DTSC to consider all of the factors outlined in §69506(c)(1-5) when selecting regulatory responses. Selecting a regulatory response is just as much a multi-dimensional process as the evaluation of alternatives. Therefore, it is necessary to weigh efficacy, cost-effectiveness, burden, effects on subpopulations, and enforcement.

B. Authority (Government Code §11349(b))¹²

1. DTSC should clarify its authority to require information generation.

The proposed regulation specifies the ways in which DTSC may collect information “that it determines is necessary” to implement this chapter. In §69501.4(a)(4) DTSC asserts its authority to “request a responsible party or a chemical manufacturer to generate new information and provide it to the Department, in accordance with a schedule specified by the Department.” In support of its assertion that it has the sweeping authority to compel the generation of any and all new information “necessary to implement this chapter,” DTSC cites to three statutory provisions, none of which in fact support the Department’s assertion of such broad authority.

The Department cites to §58012 Health and Safety Code as a basis of its authority to compel the generation of new information. That general grant of authority to “adopt and enforce rules and regulations for the execution of its duties” does not appear to add to the specific grants of authority contained with the Green Chemistry statute (AB 1879), and it is those specific grants of regulatory authority that govern.

The Department additionally cites to Green Chemistry statute §§25252 and 25253 of the Health and Safety Code as authority for its regulation requiring the generation of new information, but

¹² The legislative analysis of the final version of AB 1879 prepared by the Senate Committee on Environmental Quality (August 20, 2008) recognized that a legislative grant of authority to develop a range of regulatory responses that DTSC “may” take does not actually give DTSC a grant of authority to impose the range of requirements on the affected community. The Committee Analysis notes that while the language found in HSC §25253(b) “appears to give the department the authority to take listed actions, this is not explicitly and clearly stated in the bill. Usually, an administrative agency is given authority by the Legislature to take some action and then the authority to adopt regulations to implement the authority” (http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_1851-1900/ab_1879_cfa_20080821_111017_sen_comm.html). The legislative grant of authority to DTSC to set forth a range of possible regulatory responses it may take gives the Legislature a chance to review those proposed regulatory responses before the Legislature expressly grants DTSC the authority to impose the regulatory responses on the affected community. However, Article 6 of the proposed regulation clearly assumes the presence of express authority that the legislative analysis cited above pointedly notes is missing. We recommend that DTSC obtain an opinion from the Attorney General’s office on the scope of the legislative grant of authority to impose the identified regulatory responses, and then provide stakeholders with an understanding of how the Department will exercise its authority in compliance with the Attorney General’s opinion.

those specific grants of authority are either silent with respect to, or contradict, the Departments asserted authority in §69501.4(a)(4).

Section 25252 is simply silent on this issue, stating only that DTSC is not limited to adopting regulations that reference and use “available information from other nations, governments and authoritative bodies.” That section does not grant the Department the authority to compel a responsible party or chemical manufacturer to generate new information.

Section 25253 is also cited. That section appears to contradict the Department’s claim that it may compel entities to generate any and all information that the Department “determines is necessary to implement (the Safer Consumer Products) chapter.” Section 25253(b)(2) states only that the regulations adopted by the Department may impose “requirements to provide additional information needed to assess a chemical of concern and its potential alternatives.”

There are two key points to be made about §25253. The section merely authorizes regulations that require “additional information,” not the generation of new information. The logical reading of the word “additional” in this context is that it means existing information not otherwise available from other nations, governments and authoritative bodies. There is nothing to suggest a grant of authority to require the generation of new testing data or analyses.

Even if one reads “additional” information to mean the generation of new information, which ACC believes is incorrect, it grants authority only to require “information needed to assess a chemical of concern and its potential alternatives.” The section is not, under any conceivable reading, a grant of authority to require any and all information that the Department “determines is necessary to implement this chapter,” which could include virtually any type of new information.

ACC believes the Department should follow the three-step sequential, tiered process for collecting information set forth in §69501.4(a)(1) – (3). ACC agrees that DTSC should begin its information collection by reviewing information in the public domain that is readily available in a useable format, as laid out in §69501.4(a)(1), followed by reviewing information in the public domain that is available by subscription, and then by requesting additional, existing data from chemical manufacturers or importers. However, as set forth above ACC finds DTSC’s requirement to “generate new information”...“necessary to implement this chapter” in §69501.4(a)(4) beyond the scope of the cited authorizing statute.

2. DTSC should not establish the Chemicals of Concern List without public consideration.

ACC questions whether DTSC has the authority to establish a final list of “Chemicals of Concern” without public review and comment. §69502.3. Section 25252 of the Health and Safety Code (AB 1879) stipulates that the regulations are “to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.” Stakeholders and interested parties should be afforded the ability to review and comment on the initial Chemicals of Concern (COC) List.

A “list of lists” approach to establish the COC list may be justified by resource constraints, but DTSC must take “ownership” of the resulting list. A California list of COCs, developed by a California process, must also have a California-based process to remove substances from the list.

As proposed, the regulation permits petitions to delist a chemical from the COC list, and DTSC may do so, as long as that chemical is no longer listed on any of the underlying lists (those identified in §69502.2(a)) (emphasis added). Under the proposal, then, delisting is likely to be impossible. Substances would likely remain on the COC list indefinitely – even if they are used safely in consumer products or even if they are not used in consumer products at all. ACC urges DTSC to establish a California list-specific process for delisting chemicals.

3. Consideration of occupational exposures in the prioritization step should be reconsidered.

DTSC should reconsider its broad inclusion of workers and worker exposure as part of the product prioritization process. §69503.2. While it is appropriate to consider worker exposure in a retail setting, or perhaps worker exposure to products used in schools or hospitals or other institutional settings, we question whether DTSC has the authority to request information about workers in California or outside the State. At a minimum DTSC should understand how the information requirements may differ from CalOSHA requirements.

4. DTSC’s disclosure requirements may put confidential information at risk.

The crux of the proposed regulation is to address “Chemicals of Concern” in specific “Priority Products.” §69505.5(j)(2)(C). DTSC’s authority to require the disclosure of all known chemical ingredients in the alternative that differ from the original composition will put confidential information regarding new uses of chemicals and new products at risk. Disclosure of the new alternative formulation or composition of the chemicals in the selected alternative is outside of the scope of the regulation, and thus is outside of DTSC’s statutory authority to require.

5. Restrictions on trade secret claims threaten innovation.

DTSC’s proposed approach to trade secret claims, and to confidential chemical identity in particular, is contrary to the Agency’s objective to promote innovation in consumer products and to reduce or replace the presence of substances, in those products, considered to pose a risk of harm. As proposed, the regulation could actually hinder innovation.

In §69510(f) of the proposed regulations, DTSC impermissibly proposes an alteration to California trade secrecy law under the Uniform Trade Secrets Act that is not supported by the implementing statute. Under the proposed regulation, “trade secret protection *may not be claimed* for any health, safety, or environmental information contained in any hazard trait submission *or* any chemical identity information associated with a hazard trait submission.” Section 69510(f)(emphasis added). According to the Initial Statement of Reasons, the provision is intended to “effectuate the intent of Health and Safety Code §25257(f), which provides that trade-secret protection may not attach to ‘hazardous trait submissions for chemicals and chemical ingredients under this Article [14].’”

Section 25257(f) does not state, however, that “trade-secret protection may not attach” to hazard trait information. It simply notes that “[T]his section does not apply to hazardous trait submissions for chemicals and chemical ingredients pursuant to this Article.” (emphasis added). The mere fact that §25257 does not apply to hazard trait information does not mean that trade-secret protection may not attach to that information, it simply means hazard trait information is governed by pre-existing law (California Uniform Trade Secrets Act, Cal. Civ. Code §3426 *et seq.*), rather than the green chemistry statute. By restricting claims for trade secrecy protection for hazard trait submissions, the regulations impermissibly alter the Uniform Trade Secrets Act in excess of DTSC’s statutory authority under §25257, and must be revised.

Even if §25257(f) were interpreted to mean that trade secret protection does not attach to hazard trait information, proposed §69510(f) still exceeds the scope of the statute. The proposed regulation does not merely ban trade secrecy protection for hazard trait submission information; it also eliminates trade secret protection for “any chemical identity information associated with a hazard trait submission.” However, §25257(f) does state that it does not apply to chemical identity information associated with a submission, just that it does not apply to “hazardous [sic] trait submissions.”

The problem with the Department’s interpretation of §25257(f) is that it fails to differentiate between “hazard traits,” which are specific hazards, such as corrosivity or ignitability, and “chemical identities,” which are a separate type of information different than hazard traits. It would be unreasonable to interpret §25257(f) as preventing persons from claiming trade secret protection for chemical identity information, because chemical identity and formula information is the core of most companies’ legitimate trade secrets, as described below. Section 25257(f) speaks to are specific hazards, not chemical identity. A generic name for a specific chemical should be acceptable to DTSC as long as its specific hazard traits are disclosed. Section 69510(f) should be revised to expressly allow companies to claim trade secrecy protection for chemical identity information.¹³

In the chemical industry, trade secret chemical identities are among the most valuable intellectual property. The composition of formulations can be particularly vulnerable, especially for small and medium-sized businesses. The public disclosure of confidential chemical identities would make companies’ substantial investments readily available to their competitors, both in and outside the United States.

Health and safety studies and hazard trait information are meaningful to the public without disclosing chemical identities. Structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Generic names allow linkage to the scientific literature on similar chemicals and permit an assessment of the suitability of study methods.

¹³ Should DTSC decide to eliminate §69510(f) altogether, subsections (g) and (h) must similarly be eliminated as they have no effect independent of subsection (f).

ACC has tested whether generic names actually lead to relevant health and safety studies. In 2009, the U.S. Environmental Protection Agency changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential.¹⁴ ACC searched the generic and the chemical identity names of a number of these previously confidential substances in Toxline, a common tool to search toxicological literature. What was found should be of interest to DTSC. In many cases, a Toxline search for a generic name for a classified substance identified more studies than did a search for the corresponding CAS number or CAS name.

Other international jurisdictions, such as Canada, have adopted similar solutions, protecting confidential chemical identity in health and safety studies. Australia and Korea also provide protection from disclosure for confidential chemical identities, apparently without regard to whether they are in a health and safety study.

It is critical to California commerce and broader U.S. business interests nationally and internationally that confidential chemical identity is afforded protection as a trade secret. This regulation should not force manufacturers to decide whether to sacrifice their market share in California or their intellectual property, presumably on a global scale.

6. DTSC must prevent the disclosure of supporting information claimed as trade secret.

Under §69510(a), a person “who asserts a claim of trade secret protection” must furnish the department with twelve elements of “supporting information.” Assuming that the supporting information would itself contain trade secrets, and not wishing to require the submission of additional information for supporting information claimed as secret, DTSC stated that “if the documentation supporting a claim of trade secret protection contains information that is itself subject to a claim of trade secret protection, such supporting documentation . . . shall not itself require further supporting documentation.” DTSC cannot adopt this provision because it conflicts with the California Public Records Act in a manner not supported by §25257 of the Health and Safety Code.

There is a simple solution to this problem. Rather than require entities to submit supporting documentation that is trade secret, DTSC should require that no trade secret information be submitted as supporting documentation under §69510(a). DTSC should be able to make most trade secret determinations without receiving additional trade secret information. If additional trade secret information is not submitted, DTSC will not be obligated to ascertain its validity and protect it against accidental disclosure. Without the added expense of handling unnecessary trade secret information, this approach should reduce costs and lead to more efficient trade secrecy determinations.

In the unlikely event that DTSC is unable to make a trade secrecy determination with the initial round of non-trade secret supporting documentation, DTSC should amend the regulation to allow a specific request for additional information. The regulation should clearly state that the information being acquired is privileged under §1040 of the Evidence Code as “Official Information” because it is being acquired confidentially by DTSC in the course of its public duty

¹⁴ 74 Fed. Reg. 37224 (July 28, 2009).

under the Green Chemistry law and its disclosure is against the public interest because there is a necessity for preserving the confidentiality of the information that outweighs the necessity for disclosure in the interest of justice. So long as DTSC makes clear in the regulation that the additional supporting information is privileged “Official Information,” it will be exempt from public disclosure under §§6254(k) and 6255 of the Public Records Act without DTSC having to conduct an additional, costly trade secrecy determination.

ACC also cautions against requirements to submit large quantities of potentially sensitive personal and business information to support alternatives assessment reports. For example, the detailed supply chain information required for alternatives assessment should be eliminated, and the detailed facility and location information is not critical to the goals of the program.

C. Clarity (Government Code §11349(c))

The proposed regulation is rife with uncertainty. The uncertainties, in turn, make implementation and compliance a challenge. This lack of clarity directly contradicts the Office of Administrative Law’s standard of clarity, which mandates that regulations be “written or displayed so that the meaning . . . will be easily understood by those persons directly affected by them.”¹⁵ Below are examples of this lack of clarity.

1. DTSC should clarify the use of lists developed by other bodies.

Objective chemical selection criteria for the COC list should be used in the regulation, rather than adoption of a “list of lists” developed by other bodies. If DTSC nevertheless decides to adopt a list-based approach as suggested in §69502.2, it is critical that any such lists be developed by authoritative bodies. As proposed, it is unclear what criteria DTSC used to select the underlying lists for COC identification. It is also unclear how DTSC will characterize the chemicals on the COC list. In ACC’s view, authoritative bodies include government agencies and formal scientific organizations that:

- Characterize chemicals in an open, deliberative and transparent scientific process in which stakeholders are able to participate formally, communicating directly with the authoritative body through written and oral comments.
- Are widely perceived to be objective, scientifically based, and do not engage in advocacy.
- Base chemical characterizations on a weight-of-the-evidence approach. To the extent available, authoritative bodies consider multiple reliable studies, conducted by different laboratories, at different times, and involving not only different strains but different species and give full consideration to mode of action, confounding factors, maternal toxicity, historical controls and any other scientific information that may be relevant to understanding the potential effects of chemicals on health and the environment.
- Publish their characterizations of chemicals through governmental regulations, periodic reports, monographs or similar publications.

¹⁵ California Government Code, §11349(c).

The confidence of the public and the regulated community in the regulation will be enhanced if DTSC can assure that appropriate processes and the best scientific data available inform the list.

ACC suggests that DTSC list chemicals on the COC list by their individual Chemical Abstract Services numbers (CAS RN). The regulation should specify unique CAS RNs and cannot utilize generic chemical categories. For instance, the perfluorinated chemical category contains hundreds of different unique CAS RN chemicals, each with its own properties. Compliance and the ability to enforce the regulation require clarity regarding the COCs characterization.

Upon the effective date of the proposed regulations, a chemical would qualify as a Chemical of Concern if it (1) exhibits one of 25 environmental or toxicological hazard traits established by OEHHA in its *Toxics Information Clearinghouse* (22 CCR §§69401- 69407.2); and, (2) it appears on one of the lists specified in §69502.2(a) of the proposed rule. Several of the lists are inappropriate indicators of hazard.

1. Category 1 Endocrine Disruptors Identified in the European Commission DG Environment Report. For example, §69502.2(a)(1)(C) references a 2000 report prepared by a consultant for the European Commission entitled *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*. The preface of the report makes clear that the report was intended as “a first step towards the establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption....”¹⁶ Indeed, the “working list” of 564 chemicals proposed in the 2000 report has been modified substantially over time. 575 chemicals were ultimately screened and evaluated as to their endocrine effects.¹⁷ Of that total:

109 substances were not retained in the priority list due to insufficient data on ED effects or insufficient scientific evidence. 147 substances have been excluded from the evaluation during the process as they were identified as double entries, mixtures or of doubtful relevance.¹⁸

The 2000 report has clearly been superseded by subsequent chemical evaluations, and should not be included as a trigger for hazard classification. For this reason, we urge the Department to delete §69502.2(a)(1)(C) from the proposed rule.

Most importantly, the potential to interact with the endocrine system does not necessarily constitute a health risk. As captured in the widely adopted Weybridge Definition, “[a]n endocrine disrupter is an exogenous substance that causes adverse health effects in an intact organism, or its progeny, secondary (consequent) to changes in endocrine function.”¹⁹ The International Programme for Chemical Safety (IPCS – which includes WHO, UNEP and

¹⁶ BKH Consulting Engineers, in association with TNO Nutrition and Food Research, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, November 10, 2000.

¹⁷ European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.

¹⁸ European Commission, *Endocrine Disruptors Website*, http://ec.europa.eu/environment/endocrine/documents/sec_2007_1635_en.htm.

¹⁹ European Workshop on the Impact of Endocrine Disruptor on Human Health and Wildlife (Weybridge UK; 1996). European Union Report EUR17459.

ILO), utilizes a similar definition, “[a]n endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effect in an intact organism, or its progeny, or (sub)populations.”²⁰

Endocrine-mediated effects have already been captured by other lists, selected by DTSC that include reproductive, developmental and other adverse outcomes.

2. Group 2B carcinogens identified by the International Agency for Research on Cancer (IARC). The IARC Group 2B list is composed of substances for which there is limited human evidence and insufficient animal evidence of carcinogenicity.²¹ It is possible that chemicals classified as IARC 2B will have some evidence or carcinogenicity based on animal models, but stronger evidence against carcinogenicity from available human epidemiology studies. ACC strongly suggests that the IARC 2B characterization be removed from §69502.2(a)(1)(I).

Under IARC guidance, there are a number of issues when evaluating chemicals with “limited evidence of carcinogenicity,” and therefore a definitive evaluation of cancer hazards cannot be made. For example, a definitive evaluation may be difficult due to the following: the evidence of carcinogenicity is restricted to a single experiment; there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies; the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential; or, the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.²²

3. National Toxicology Program, Office of Health Assessment and Translation Reproductive or Developmental Toxicant. Another list that is inappropriate for purposes of qualifying COCs is proposed in §69502.2(a)(1)(L). That provision refers to “reproductive or developmental toxicants identified” in monographs produced by the National Toxicology Program, Office of Health Assessment and Translation (OHAT). OHAT is the successor to the Center for the Evaluation of Risks to Human Reproduction (CERHR).

A brief background on how CERHR/ OHAT monographs are structured demonstrates why §69502.2(a)(1)(L) is an inappropriate factor in designating Chemicals of Concern under the California Green Chemistry Program. CERHR/OHAT monographs classify chemicals based on:

- (1) the weight of scientific evidence on adverse effects, expressed on a seven-part scale ranging from “clear evidence of adverse effects” to “clear evidence of no adverse effects”; and

²⁰ World Health Organization International Program on Chemical Safety, “Global Assessment of the State-of-the-Science of Endocrine Disruptors,” WHO/PCS/EDC/02.2, Chapter 1: Executive Summary.

²¹ World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, p. 23 (<http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>).

²² World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble to the IARC Monographs, B. Scientific Review and Evaluation, 6. Evaluation and rationale (b) Carcinogenicity in experimental animals (<http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php>).

(2) the agency's level of concern that a chemical is associated with various reproductive and developmental effects, expressed on a five-part scale ranging from "serious concern for adverse effects" to "negligible concern for adverse effects."

In the second analysis, the agency may also find that "insufficient hazard and/or exposure data" exists.

A CERHR monograph can therefore determine that a particular chemical presents "clear evidence of no adverse effects" and express "negligible concern for adverse effects." Nevertheless, under a plausible interpretation of §69502.2(a)(1)(L), that chemical could be qualified as a Chemical of Concern because it was "identified" in a CERHR/OHAT monograph. We respectfully recommend that §69502.2(a)(1)(L) be eliminated from the proposed rule, or alternatively, that DTSC make clear that *only CERHR/OHAT monographs indicating high levels of evidence and concern* regarding reproductive and developmental effects be considered as the basis for addition to the COC list.

2. DTSC should make clear how it will use the key criteria to identify priority products.

As proposed, it is unclear how DTSC will objectively utilize the "Key Criteria" to assess and prioritize products based on a list of over twelve hundred potential chemicals of concern. §69502.3(b). An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint, as it leaves the door open for political decision-making.

The incorporation of "the ability of the Chemical of Concern in a product *to contribute to or cause* adverse public health and/or environmental impacts," (emphasis added) as criteria for prioritization is unclear. This phrasing is contrary to a risk-based approach in the implementation phase of prioritization and strays from the statutory use of the term "potential to cause." ACC suggests DTSC revise this phrase to read, "The *potential* for the Chemical(s) of Concern in a product *to cause* adverse public health and/or environmental impacts...".

The proposed "narrative standard" for the prioritization process (§69503.3 of the proposed rule) also creates significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the proposed rule does not articulate a clear, step-by-step process for doing so. The proposal indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC, in fact, might use to reach a decision.

The proposed regulation lays out multiple criteria to be used in prioritizing products for review, with products meeting "one or more" of the key criteria to be considered priorities. The

regulation should be clarified to focus, at least in the first few years of the program, on products that meet all three statutory criteria (as high priorities).²³

From the proposal, it appears that the key prioritization criteria are secondary to the longer list of other criteria that precedes the “Key Criteria” (§69503.2). DTSC should clarify the relationship between the key criteria and what is better characterized as supporting evidence.

Other information DTSC proposes to use, however, is too ambiguous and may not be appropriate as part of this exercise, or may be claimed as confidential information. The proposed rule states, “[t]he Department shall consider the potential adverse public health and environmental impacts...” associated with a number of hazard and exposure scenarios. This information may be extremely diffuse, poorly defined or difficult to obtain, reliably, for the department to consider.

For example, the proposal specifies that DTSC shall give special consideration to the type and severity of potential adverse impact(s), and the potency of the chemical(s) associated with the adverse impact(s), for children, pregnant women, and other sensitive subpopulations. ACC agrees that certain demographics, primarily children, should be given distinct consideration. However, the term “sensitive subpopulations” as defined by DTSC in the proposed regulation is a vague and highly subjective term (“including but not limited to” §69501.2(a)(72)) that may include different demographics or conditions depending on the context. See “sensitive subpopulations” under Clarity, Definitions above.

In many cases it will be difficult to obtain product exposure information relating to “manufacturing, use, storage, transportation, and end-of-life management practices and the locations of these practices.” The proposed regulation seems to expect consumer product manufacturers to have comprehensive manufacturing, use, distribution, and disposal data for every unit of its product. This is not a practical expectation. It becomes increasingly difficult to monitor the exact movement of products once they are sold to distributors and to primary and secondary retailers.

Similarly, with the exception of a few product categories, most consumer products find their way to a landfill or recycle stream at the end of their useful life, although it is often difficult to track the exact path of the product. As DTSC is surely aware, end of life management practices are commonly predisposed by municipalities in which the products reach the end of their useful lives, rather than by manufacturer or retailer plans. A manufacturer would clearly not know that location at the time of production or sale. The regulation should hold regulated entities accountable only for information that it can be reasonably expected to obtain.

The proposed rule indicates DTSC will consider the availability of reliable information to substantiate potential adverse impacts and exposures in the prioritization process. ACC believes that DTSC should also consider reliable evidence that refutes potential adverse impacts or exposures.

²³ Three statutory criteria: 1) The volume of the chemical in commerce in this state; 2) The potential for exposure to the chemical in a consumer product; and, 3) Potential effects on sensitive subpopulations, including infants and children.

3. DTSC should clarify the process for evaluation of aggregate and cumulative effects.

The proposed rule fails to mention what framework DTSC will use, as well as what framework(s) responsible entities may use, during the alternatives assessment process to evaluate aggregate and cumulative risk. §69503.2(a)(1)(A)1.b./c.²⁴ ACC urges DTSC to specify what process will be used to determine when an aggregate and cumulative risk assessment is necessary, and, what framework will be used to do so. Specifically, DTSC should clarify whether it is referring to both an assessment of human health aggregate and cumulative risks, and, environmental aggregate and cumulative risks.

It is impractical to require an assessment of aggregate and cumulative risk for all chemicals of concern or all priority products. Assessing aggregate risks from the total exposure to a specific chemical from all different sources and routes requires considerable data, about each and every use of a substance, information that manufacturers of individual products do not have and cannot readily obtain. Aggregate assessments should only be required for those chemicals that meet specific criteria, such as cases that present a very narrow margin of exposure.

The assessment of cumulative risk – the evaluation of a common toxic effect from a concurrent exposure to a group of chemical and non-chemical risks that act in the same way poses even greater challenges. Similar to aggregate risk assessment, cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. Cumulative risk assessment may require manufacturers to look at all the adverse effects caused by the chemical in question, and to evaluate all other chemicals that potentially cause the same adverse effects (not just those in humans, but also in animal studies where doses are typically hundreds, thousands or even tens of thousands of times higher than humans ever experience). In the context of consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

ACC urges DTSC to adopt the best available framework regarding combined exposure to multiple chemicals, developed and endorsed by the World Health Organization (WHO)/ International Program on Chemical Safety (IPCS) (see attached). The framework is designed to aid risk assessors in identifying priorities for risk management for a wide range of applications where co-exposures to multiple chemicals are expected; and, it builds on previously published guidance for priority setting and assessment of combined exposures.²⁵ A framework assessment would provide DTSC with a problem formulation process for each combined exposure situation. Roughly, DTSC would begin by asking a series of questions to formulate the problem, and then for example, the initial Tier 1 assessment would begin with the upper-bound levels of daily intake for the majority of the identified population (exposure), and, potency for the most sensitive endpoint (hazard). Based on necessity, DTSC may then revise the exposure and hazard assumptions, replacing with increasingly detailed data and models.

²⁴ The proposed regulation refers to “aggregate effects” and “cumulative effects,” whereas typically these are referred to as “aggregate risk” and “cumulative risk.”

²⁵ M.E. (Bette) Meek, Alan R. Boobis, Kevin M. Crofton, et al, “Risk assessment of combined exposure to multiple chemicals: A WHO/IPCS framework,” *Regulatory Toxicology and Pharmacology*, v 60 (2011) S1-S14, p 51.

4. Minimum Detectable Concentrations should not be the alternative analysis threshold.

Language in the ISOR suggests that the default Alternatives Analysis Threshold (AAT) will be the minimum detectable concentration for intentionally added chemicals:

Section 69503.5, in its entirety, provides an exemption from the requirement of conducting an alternatives analysis for a Priority Product when specified criteria are met. The distinction between those Priority Products that are subject to the alternatives analysis and those that are exempt will be primarily based on the minimum detectable concentration for the Chemical of Concern and the difficulty of avoiding the presence of contaminants that are the source of the Chemical of Concern.

Functionally speaking, the detectable concentration or limit of detection is the lowest possible level of the chemical in the product. Beyond the limit of quantitation, detection may only be a binary (present/not present) outcome, rather than a quantitative amount. If this is the case, DTSC has not been clear about how the AAT will be used to demonstrate reductions of COC in the Priority Products. AB 1879 establishes that both limiting exposure to the COC(s) or reducing the level of hazard posed by a COC are goals of the regulation.²⁶ What is less apparent, however, is how a responsible entity will be able to demonstrably reduce the level of a COC in the Priority Product below the limit of detection. ACC asks that DTSC clarify whether the limit of detection will be the preferred AAT.

Satisfying DTSC's AAT exemption requirements will be a significant analytical burden for product manufacturers. At a minimum considerable product testing will be necessary to substantiate the exemption, and that the AAT will likely be at the level of detection. Most industrial chemicals are not pure; in essence many are mixtures.

As proposed, the regulation does not distinguish between intentionally-added constituents and contaminants, and every product might have a trace amount of a COC and would require analysis. Furthermore, responsible entities cannot control the state or pace of analytical chemistry. Establishing the limit of detection as a regulatory threshold effectively sets a moving target. The degree to which small and medium sized businesses, much less importers and retailers, would have access to and resources to put toward this level of analytical chemistry is questionable and impractical.

Furthermore, the proposed AAT threshold and the process for establishing the AAT are not consistent with the processes used by federal and international agencies. ACC strongly recommends that DTSC set numerical thresholds that are harmonized with those applied by federal and international agencies. This would be consistent with the enacting statute that specifies

[T]he department shall reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have

²⁶ Assembly Bill 1879, Section 1.

undertaken similar chemical prioritization processes, so as to leverage the work and costs already incurred by those entities and to minimize costs and maximize benefits for the state's economy.

The federal Occupational Safety and Health Administration (OSHA), the Globally Harmonized System for Classification and Labeling (GHS), and the European Union's REACH standard apply a *de minimis* threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens and reproductive toxins. Further, ACC urges DTSC to distinguish between intentionally-added chemical ingredients and contaminants, and subject contaminants to a higher threshold.

The AA process also warrants other clarifications. Section 69505.4(a) does not make clear what criteria will be used to judge when an when an alternative makes a “demonstrable contribution” to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product. Section 69505.5(d)(5) fails to articulate what bearing the proximity of the place of product manufacture to virgin or recycled resources has on a DTSC decision. At a minimum, this information could very well be commercially sensitive, pertaining to the costs of doing business, and it will likely be claimed as trade secret.

5. Many definitions should be clarified.

- “Adverse air quality impacts” (§69501.1(a)(3)). It is unclear what is meant by “air emissions of any of the air contaminants . . . *that have the ability* to result in adverse public health, ecological, soil, or water impacts,” (emphasis added). It is not clear what this means in practice. For example, it is not clear what DTSC intends by referencing air contaminants with an “ability” to produce adverse impacts. “Alternative” (§69501.1(a)(11)(C)). The meaning of “redesign of a Priority Product and/or manufacturing process, *using different materials* to reduce or restrict exposures to Chemicals of Concern in the Priority Product,” (emphasis added) is not clear. DTSC should consider eliminating the phrase “using different materials.” “Hazard trait submission” (§69501.1(a)(33)). The proposed regulation states that “[W]hen any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission.” According to OEHHA’s Green Chemistry Hazard Trait Characteristics, every chemical will manifest some hazard trait. This provision, therefore, is meaningless.
- “Homogeneous material” (§69501.1(a)(34)).DTSC proposes to identify and prioritize specific materials, regulating specific uses of a material. The definition of “homogenous material” is taken directly from the European Union’s Restriction of Hazardous Substances Directive (RoHS). “Homogeneous material” is not well-defined, however, as it may be “one material of uniform composition” or “a material, consisting of a combination of materials.” Attempting to harmonize with a problematic term will make compliance difficult for both DTSC and responsible entities.

ACC suggests that DTSC remove the term from the regulation and make a consequent revision in the definitions of “component,” as well as “consumer product” or “product” as suggested below:

(21) “Component” means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:

- (A) Is required to complete or finish an item
- (B) Performs a distinctive or necessary function in the operation of a product or part of a product
- (C) Is intended to be included as a part of a finished item

(22)(A) “Consumer product” or “Product” means any of the following:

1. A “consumer product” as defined in Health and Safety Code §25251;
2. A component, or uniquely identifiable material within a component, that is identified under §69503.4(a)(2)(B), as the minimum required focus of an AA.

- “Reliable information” (§69501.1(a)(52)). The definition of “reliable information” lacks rigor and lacks a weight-of-the-evidence evaluation. However, the ISOR discussion of “reliable information” includes a number of internationally-accepted testing guidelines and protocols. It is not clear why these guidelines and protocols not been included in the regulatory language.²⁷ ACC urges DTSC to include these guidelines, practices and protocols in the regulation, and to specifically note:
- Whether the study has been replicated;
- Whether the study provided was conducted according to generally accepted principles, including test protocols:
 - US FDA Good Laboratory Practices (Part 58 of Title 21 of the Code of Federal Regulations)
 - US EPA’s Office of Chemical Safety and Pollution Prevention Harmonized Test Guidelines
 - TSCA (Chapter 1 of Title 40 of the Code of Federal Regulations)
 - TSCA Testing Guidelines (Parts 798 and 799 of Title 40 of the Code of Federal Regulations)
 - OECD Guidelines for Testing of Chemicals
 - OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring
 - OECD Manual for Investigation of High Production Volume Chemicals
 - REACH/ECHA Guidance on Information Requirements and Chemical Safety Assessment and Regulation (EC) No. 440/2008 of the European Parliament and the Council
 - CEPA Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers.
- “Responsible Entity” (§69501.1)(a)(54)). For clarity and consistency with other existing regulations ACC suggests that DTSC adopt a definition of “manufacturer” that is consistent with the Fair Packaging and Labeling Act (FPLA; 15 U.S.C. §§1451-1461).

²⁷ See, however, Initial Statement of Reasons: Safer Consumer Products, R-2011-02, <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>, p. 33-34.

For products manufactured in a foreign country and imported into the U.S., FPLA requires that the entity that receives the product shipment in the U.S. must assure that the product carries U.S.-compliant labeling that identifies the entity for which the product is “manufactured for” or “distributed by.” It is practical for DTSC to start with the entity identified on the product label pursuant to FPLA requirements as an initial point of contact for imported products rather than assign the duty to comply to a foreign manufacturer or retailer.

- “Sensitive subpopulations” (§69501.1)(a)(58)). It is not clear what DTSC means by sensitive subpopulations representing “a meaningful portion of the general population?” The definition of “sensitive subpopulations” is too broad and may present significant issues of compliance for responsible entities depending on how this term is interpreted. There is likely broad agreement that infants, children, pregnant women, elderly individuals, and individuals with a history of serious illness should be included within the definition. However, the use of the phrase “including, but not limited to...” inappropriately confers upon the Department unlimited and arbitrary discretion to define the universe of “sensitive subpopulations” in ways that the regulated community cannot anticipate. DTSC should carefully review the proposed regulation for such instances of open-ended language such as the definition of “sensitive subpopulations” in this and other sections, giving careful consideration to the inability of product manufacturers, importers, and retailers to comply with such vague regulatory language that could give rise to shifting interpretation over time.

It is similarly not clear why the proposed regulation include workers and their occupational exposures as a “sensitive subpopulation?”

- “Technically and economically feasible” (§69501.1)(a)(59)). It is not clear what DTSC means when it indicates that “[t]he technical knowledge, equipment, materials, and other resources available in the marketplace *are expected to be sufficient* to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period,” (emphasis added). ACC believes a better articulation would be that the information “are sufficient.” ACC supports DTSC’s incorporation of consumer acceptance as part of the overall feasibility of a potential alternative.

6. The bulk chemical exemption should be restored.

The goal of the California Green Chemistry Initiative is to provide better, safer options to California consumers, in terms of the products they use on a daily basis. The focus of the “Safer Consumer Product Regulation” is the “Chemical(s) of Concern” in a particular “Priority Product.” Therefore, ACC is unclear why DTSC has included bulk chemicals within the scope of a “consumer product.” Federal agencies and federal statutes regulate chemicals and materials; and federal statutes and agencies, such as the Occupational Safety and Health Administration (OSHA) regulate the manufacturing workplace, as well as the Division of Occupational Safety and Health (Cal/OSHA), within California. Furthermore, the Department of Transportation and Department of Homeland Security also regulate the movement and transport of chemical goods.²⁸ ACC recommends that the exemption be restored.

²⁸ See attached list of federal statutes that currently regulate chemicals in U.S. commerce.

7. DTSC should clarify certain information submission and retention requirements.

The purpose of §69501.3(d) is unclear, and DTSC should clarify its intention. The provision states:

A person who is subject to a requirement to obtain or prepare information, but who is not required to submit the information to the Department or has not yet been requested to submit information to the Department, shall retain the information for a period of three (3) years following the date the person was required to obtain or prepare the information.

A literal reading of the provision would require persons not subject to the regulation (those not required to submit information) to retain information for up to three years. All required information will be submitted to DTSC in some format. ACC requests that DTSC provide an example of the type of information referenced in the provision and the type of person expected to be affected.

Similarly, Section 69501.4(a)(1-4) also fails to make clear who may be responsible for information submissions in the future. In addition, §69501.4(d) does not make clear what information DTSC would consider “helpful” to the Department. ACC suggests using the term “reliable information” in this instance.

8. Additional clarity on the standard for demonstrating an inability to respond should be provided.

The last provision of §69501.5(c) describes the process by which the responsible entity, chemical manufacturer or importer may find itself on the Response Status List. The responsible party in this case must demonstrate to DTSC’s “satisfaction that it does not have and is unable to produce the requested information” or, DTSC may post the responsible party’s identifying information on DTSC’s web site. However, it is unclear how a responsible entity, chemical manufacturer or importer may demonstrate to the Department’s satisfaction that it is not able to produce the requested information. For example, DTSC might better articulate the objective standard of proof for such demonstrations.

9. DTSC should address its intention to respond to public comments.

Transparency in DTSC’s processes is crucial, and therefore, DTSC should clarify the role of the Department in responding to public comments. See, e.g., §69502.3(d). The success of DTSC’s regulation depends in large part on the degree to which the compliance and decision making processes are transparent. It is good practice to require DTSC to respond to any and all substantive public comments, but the proposal lacks this basic process protection. For example, the COC listing process allows DTSC the discretion to respond to “some or all” public comments received on revisions to the list. Regulated entities materially affected by DTSC’s decisions, and the public, should be able to understand the basis for the decisions, and DTSC’s

reasoning in accepting or rejecting particular recommendations, data, and/or information. ACC strongly recommends that DTSC's default approach be to respond to all public comments.

10. DTSC's requirement to apply for an exemption from the response requirement places a significant burden on the regulated community, and appears inconsistent with the statute.

Section 69506.11 is intended to implement the provision in §25257.1 of the statute. Subdivision (b) of the statute provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides requires the Department to reform from duplicating or adopting conflicting regulations for product categories already regulated or subject to pending regulation.

Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response "substantially duplicates" one or more requirements of another California or federal regulatory program, "without conferring additional public health or environmental protection benefits." ACC requests that the Department clarify this section based on the following three points:

- Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The Legislature imposed the responsibility on the DTSC to implement that provision. It does not contemplate imposing the burden on responsible entities.
- With respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. This provision exceeds the Department's authority. Nothing in the section contemplates that DTSC or the Department may duplicate other regulatory programs solely on the Department's contention that greater public health or environmental protection will result.
- The Department has ignored the fact that subdivision (b) of §25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, may well supersede the other agency's regulatory program.

D. Consistency (Government Code §11349(d))

As noted in earlier sections, elements of the proposed regulation appear to be inconsistent with the Uniform Trade Secrets and Public Records Act, certain CalOSHA worker safety requirements, and certain federal OSHA and international standards. ACC strongly recommends that DTSC ensure that these inconsistencies are resolved in the final regulation.

E. Nonduplication (Government Code §11349(d))

Two areas of the proposed regulation appear to duplicate other regulatory programs. Section 69501 does not exempt food contact materials from the scope of the regulation, and thus

duplicates the Federal Food, Drug and Cosmetic Act (FFDCA). The federal Food and Drug Administration regulates food contact materials through a comprehensive, science-based regulatory framework. Any DTSC regulation of food contact materials would necessarily be duplicative of the federal regulatory effort. At a minimum, it is not clear what additional level of health or environmental protection California would confer to food contact materials beyond the extensive and costly federal governmental reviews conducted by highly trained scientific staff with years of experience.

Similarly, the proposed addition of “workers” as a potentially sensitive subpopulation appears to duplicate the existing authority of Cal/OSHA to protect workers from unreasonable exposures to chemicals. California State Plan, §19 OSHA (1970), approved May 1, 1973, and certified August 19, 1977. Per the agreement between the State of California and OSHA, the state plan “applies to all public and private sector places of employment in the state, with the exception of Federal employees, the United States Postal Service, private sector employers of Native American lands, maritime activities on the navigable waterways of the US, private contractors working on land designated as exclusive Federal jurisdiction, and employers that require Federal security clearances.” See also, 29 CFR 1952.172. At a minimum, DTSC should explain how the inclusion of workers as a potentially sensitive subpopulation does not duplicate CalOSHA’s authority.

Federal Statutes Regulating Chemicals

Abbreviation	Statute	Brief Summary
1. TSCA	Toxic Substances Control Act 15 U.S.C. §§ 2601 – 2695d	<ul style="list-style-type: none"> • Requires premanufacture notification for all new chemicals not on the TSCA Inventory; authorizes Environmental Protection Agency (EPA) to restrict new chemicals of concern • Authorizes EPA to require periodic reporting of information about chemicals, including manufacturing and use data and health and safety studies • Requires reporting of information that reasonably supports the conclusion of substantial risk • Authorizes EPA to require data submission (akin to premanufacture notice) before companies engage in “significant new uses” of chemicals • Authorizes EPA to issue test rules, and reporting rules for chemicals it finds may pose an unreasonable risk; chemicals may also be tested by industry through voluntary programs under TSCA • Authorizes EPA to require testing to meet good laboratory practice standards and validated protocols • Authorizes EPA to ban or restrict chemicals that pose an unreasonable risk to human health or the environment • Requires certification of TSCA compliance for all imported chemicals • Requires notification to EPA of export of chemicals that have been restricted in the United States • Supports EPA initiatives to prioritize and review chemicals and take regulatory actions to restrict chemicals where EPA deems necessary
2. FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act 7 U.S.C. §§ 136 – 136y	<ul style="list-style-type: none"> • Requires all pesticide products and their active ingredients, including antimicrobials and certain kinds of preservatives, to be registered prior to sale • Registration requires data showing that the pesticide is effective and does not pose an unreasonable risk to man or the environment; burden of proof is on pesticide manufacturer

Abbreviation	Statute	Brief Summary
		<ul style="list-style-type: none"> • Authorizes EPA to require testing to meet good laboratory practice standards and validated protocols • Requires registration of producing establishments • Requires annual production reporting • Requires reporting of adverse effects information • Requires certification of FIFRA compliance for imported pesticides • Requires detailed package labeling • Requires notification of export of unregistered pesticides
3. FFDCA	Federal Food, Drug, and Cosmetic Act 21 U.S.C. §§ 301 – 399d	<ul style="list-style-type: none"> • Prohibits the sale of any food, drug, medical device, or cosmetic that is adulterated or misbranded • Requires premarket approval of food additives, color additives, new dietary ingredients, drugs, and medical devices, including their components, based on a showing that they are safe • Requires producers of food additives that are not “generally recognized as safe” to demonstrate to a reasonable certainty that no harm will result from the intended use of their additives • Broadly defines “food additive” to include small transfers from food packaging materials
4. FQPA	Food Quality Protection Act 110 Stat. 1489, amending FIFRA and FFDCA	<ul style="list-style-type: none"> • Requires EPA to set tolerances, or maximum safe residue limits, for pesticide residues on foods • Expands EPA authority over food contact substances, e.g. antimicrobials in or on food packaging • Includes special protections for infants and children • Requires EPA to expedite approval of reduced risk pesticides
5. CAA	Clean Air Act 42 U.S.C. §§ 7401 – 7671q	<ul style="list-style-type: none"> • Sets mandatory performance levels for reducing emissions of toxic air pollutants from various categories of industrial facilities • Requires plans for the prevention of emergency releases to air of highly toxic chemicals • Requires air pollution sources to meet emission limits and obtain permits from EPA or states • Requires reporting and recordkeeping under the permits • Requires phasing out of production and use of ozone-destroying chemicals and encourages the development of “ozone-friendly” substitutes

Abbreviation	Statute	Brief Summary
6. FWPCA / CWA	Federal Water Pollution Control Act (Clean Water Act) 33 U.S.C. §§ 1251 – 1387	<ul style="list-style-type: none"> • Controls chemical discharges of pollutants to waters through the National Pollutant Discharge Elimination System (NPDES) permit program • Imposes both technology-based standards and effluent guidelines • Operates pretreatment program for industrial facilities that discharge chemicals in waste water into municipal sewer systems
7. SDWA	Safe Drinking Water Act 42 U.S.C. §§ 300f – 300j-26	<ul style="list-style-type: none"> • Requires EPA to set national health-based standards for chemicals and other contaminants in drinking water • Requires public water systems to test for contaminants and meet drinking water standards; operators must be certified
8. RCRA/ SWDA	Resource Conservation and Recovery Act, amending the Solid Waste Disposal Act 42 U.S.C. §§ 6901 – 6992k	<ul style="list-style-type: none"> • Gives EPA “cradle-to-grave” authority to control hazardous waste • Requires hazardous waste identification and tracking • Establishes extensive permitting and operating requirements for hazardous waste generators, transporters, treatment facilities, storage facilities, and disposal facilities • Requires corrective action to clean up releases of hazardous wastes or hazardous waste constituents at RCRA-regulated sites • Provides framework for management of non-hazardous solid waste
9. CERCLA / Superfund	Comprehensive Environmental Responsibility, Compensation, and Liability Act 42 U.S.C. §§ 9601 – 9675	<ul style="list-style-type: none"> • Establishes processes and standards for clean-up of hazardous waste sites and removal and remediation of contaminants • Imposes strict liability for clean-up for potentially responsible parties, including prior owners/operators, entities that arranged for waste disposal, and others, thereby ensuring that care is taken against chemical releases going forward to avoid this liability • Establishes National Oil and Hazardous Substance Pollution Contingency Plan (NCP) • Created the Agency for Toxic Substances and Disease Registry (ATSDR) within CDC Public Health Service, and other offices
10. EPCRA	Emergency Planning and Community Right-to-Know Act 42 U.S.C. §§ 11004 – 11050	<ul style="list-style-type: none"> • Requires companies to submit detailed annual reports on releases and transfers of certain toxic chemicals (Toxic Release Inventory or TRI reporting); makes reported data publicly available • Requires every community in the United States to be part of a comprehensive emergency response plan; facilities must participate in the planning process

Abbreviation	Statute	Brief Summary
		<ul style="list-style-type: none"> • Requires companies to maintain material safety data sheets (MSDSs) for hazardous chemicals and to submit the MSDSs or lists of chemicals, and annual inventory of these chemicals, to state and local emergency planning entities and the local fire department (Tier I or Tier II reporting) • Requires immediate notification of accidental chemical releases to state and local emergency planning entities • Requires notification of the presence of high quantities of listed “extremely hazardous substances” to state and local entities
11. PPA / P2 Act	Pollution Prevention Act 42 U.S.C. §§ 13101 – 13109	<ul style="list-style-type: none"> • Requires companies to file an annual toxic chemical source reduction and recycling report along with TRI report • Requires EPA to consider the effects of its regulations on reduction of pollution production at the source and to coordinate with other agencies to promote source reduction • Creates a Source Reduction Clearinghouse to foster information exchange on source reduction techniques and technical assistance for businesses • Provides grants to states for source reduction programs
12. OSH Act	Occupational Safety and Health Act 29 U.S.C. §§ 651 – 678	<ul style="list-style-type: none"> • Establishes wide-ranging hazard communication program • Requires manufacturers and importers of hazardous materials to conduct hazard evaluations of the products they manufacture or import • Requires labels and material safety data sheets for hazardous materials at the workplace and accompanying initial shipments to new customers • Requires companies to provide personal protective equipment and training to protect against chemical and other workplace risks • Requires recordkeeping of workplace injuries and illnesses and reporting of serious incidents • Maintains Occupational Chemical Database with EPA • Established the National Institute of Occupational Safety and Health (NIOSH) which researches, inter alia, chemical safety
13. HMTA	Hazardous Materials Transportation Act 49 U.S.C. §§ 5101 – 5127	<ul style="list-style-type: none"> • Requires identification of potential hazards (including toxicity, flammability, corrosivity, etc.) of transported materials and

Abbreviation	Statute	Brief Summary
		<p>products</p> <ul style="list-style-type: none"> • Requires hazard communication (shipping papers, package marking and labeling, and vehicle placarding) for various classes of hazardous materials including listed materials, hazardous wastes, and marine pollutants • Specifies packaging safety requirements • Specifies operational and training requirements for transportation of chemicals and hazardous materials by various modes (air, water, road, rail, pipeline) • Administered by Department of Transportation’s Pipeline and Hazardous Materials Safety Administration
14. CPSA / CPSIA	Consumer Product Safety Act, as amended by the Consumer Product Safety Improvement Act 15 U.S.C. §§ 2051 – 2089	<ul style="list-style-type: none"> • Establishes independent Consumer Product Safety Commission • Governs manufacturers (including importers), distributors, and retailers • Sets preference for consensus voluntary private sector standards (e.g. ANSI, ASTM) but authorizes CPSC to impose mandatory standards for product safety • Restricts lead paint and phthalates in children’s products or child care articles • Requires labeling, tracking, third party testing and certification for children’s products • Requires general conformity certification with each shipment • Requires reporting of product defects or non-compliance with mandatory standards • Enforced by retail, import, and internet surveillance
15. PPPA	Poison Packaging Prevention Act 15 U.S.C. §§ 1471 – 1477	<ul style="list-style-type: none"> • Requires CPSC to establish standards for special packaging of any household chemical, including fuels, cosmetics, and other substances customarily stored by households, in order to protect children from hazards • Makes alternative labeling option available where child-protective packaging would make the household substance unavailable to elderly or disabled persons
16. FHSA	Federal Hazardous Substances Act 15 U.S.C. §§ 1261 – 1278	<ul style="list-style-type: none"> • Requires container labeling for hazardous household products to help consumers safely store and use those products and to give

Abbreviation	Statute	Brief Summary
		<p>information on first aid</p> <ul style="list-style-type: none"> • Authorizes the CPSC to ban certain products that are so dangerous or the nature of the hazard is such that labeling is not adequate to protect consumers
17. FPLA	Fair Packaging and Labeling Act 15 U.S.C. §§ 1451 – 1461	<ul style="list-style-type: none"> • Requires each package of household consumer commodities to bear a label on which there is information necessary to prevent consumer deception • Administered by the Federal Trade Commission and FDA
18. CSA	Controlled Substances Act 21 U.S.C. §§ 801 – 971	<ul style="list-style-type: none"> • Restricts the manufacture, import, export, distribution, and use of chemicals which are narcotics or can be used to make narcotics • Administered by the Drug Enforcement Administration in the Department of Justice and by FDA
19. CFATS	Department of Homeland Security Appropriations Act 6 U.S.C. § 121 note	<ul style="list-style-type: none"> • Authorizes the Department of Homeland Security (DHS) to establish risk-based Chemical Facility Anti-Terrorism Standards for the security of chemical facilities • DHS assigns facilities to one of four risk tiers; different assessment and planning obligations are imposed for the different tiers
20. CWC	Chemical Weapons Convention Implementation Act 22 U.S.C. §§ 6701 – 6771	<ul style="list-style-type: none"> • Authorizes reporting of information about chemicals that may be used to make chemical weapons • Authorizes international inspection of facilities where chemicals that may be used to make chemical weapons are present • Administered by the Department of Commerce’s Export Administration and by the Department of State

Attachment: Estimated Industry Costs

This analysis provides an explanation of the assumptions and estimates used to develop potential industry costs associated with the proposed Safer Consumer Product (SCP) regulations under Title 22 of the California Code of Regulations (CCR 22).

The purpose of this analysis is to present estimates of the direct costs to an entity for the initial preparation of an Alternatives Assessment (AA). Any industry costs that might be incurred for preparing and submitting notifications, petitions, requests, comments, and any additional information or documents requested by the Department are not considered herein.¹ In summary, the completion of one AA will generally range from approximately \$1,958 to \$15,130. During the first round of Priority Products—i.e., in the first year—it is assumed that small and medium enterprises (SMEs) will prepare one to two AAs and large enterprises will prepare two to three AAs under CCR 22. Therefore, the total cost range to prepare AAs for SMEs and large enterprises is estimated to be approximately \$1,958 to \$30,261 and \$3,916 to \$45,391, respectively.

Industry Costs per Alternative Assessment

As shown in Table 1, three employee categories of labor (clerical, technical, and managerial) were used in this cost analysis. Rates and hours were assigned based on the estimated costs to prepare and submit a Premanufacture Notice (PMN) Form to U.S. EPA Office of Toxic Substances as part of the implementation of Section 5 of the Toxic Substances Control Act (TSCA).

Table 1. Estimated Industry Labor Costs per Alternative Assessment (AA)

	Clerical	Technical	Managerial	Total
Hours^a	8 - 40	27 - 67	8 - 37	43 - 344
Cost per Hour^{b, c}	\$17	\$42	\$85	-
Total Cost	\$136 - 678	\$1,144 - 11,316	\$678 - 3,136	\$1,958 - 15,130

^a Assumed the hours to prepare and submit PMN form would be comparable to the hours to prepare and submit an AA.

^b Costs include direct salaries and benefits, but do not include corporate overhead.

^c A specific inflation rate was calculated to account for the price increase from the 1979 Arthur D. Little, Inc. estimates.

Sources: Estimated Costs of Preparation and Submission of Reproposed PMN Form (Arthur D. Little, Inc. 1979) and Price Indexes for Gross Domestic Product (U.S. Department of Commerce 2012a)

For each alternative chemical being considered, responsible entities are also required to evaluate the toxicological and environmental endpoints to identify any potential adverse public health and/or environmental impacts. The generation of this data for a single chemical could be costly for responsible entities. A basic set of test data can cost approximately \$200,000 per chemical

¹ Costs associated with providing the Department with any of the following have not been included in the industry cost burdens estimated in this report and could pose additional costs for responsible entities: Priority Product Notifications; Priority Product Removal Notifications; Priority Product Replacement Notifications; Priority Product Cease Ordering Notifications; Alternatives Analysis Threshold Exemption Notifications; Chemical of Concern Removal Notifications; Trade Secrets; Petitions; and any other subsequent information requested by the Department.

(U.S. EPA 1997). Table 2 below summarizes other potential testing costs that might be associated with evaluating alternative chemicals.²

Table 2. Potential Toxicological Test Costs for Alternative Chemicals

Test Type	Associated Costs*
Carcinogenicity	\$1.1 million (for a mouse study) to ~\$5 million
Reproductive Toxicity	\$700,000 to \$1,000,000
Developmental Toxicity	\$250,000 to \$300,000
Neurotoxicity	\$700,000 to \$1,000,000
Immunotoxicity	~\$86,000
Endocrine Screening	\$400,000 to \$1 million
Respiratory Toxicity	\$82,000
Acute Oral Toxicity	\$4,000 to \$32,000
Acute Inhalation Toxicity w/ Histopathology	\$25,000
90-day Subchronic Oral Toxicity	\$150,000 to \$200,000
2-year Chronic Oral Toxicity	\$750,000 to \$1 million
Mutagenicity Screen	\$4,000 to \$6,000

Industry Costs per Entity

Alternatives Assessments must be submitted by “responsible entities,” which are defined under the proposed SCP regulations to include manufacturers, importers, distributors, retailers or any other entity that has a contract with an importer, distributor, or retailer. Assumptions about the number of entities were based on available data on the number of firms by employment sizes for the United States, as well as ICF estimates.

Of particular concern are the financial impacts that the proposed SCP regulations might have on SMEs, which make up approximately 98% of the affected firms. A universally accepted definition of an SME does not exist within the U.S. government (USITC 2010). However, according to Article 11 § 69311 of the DTSC September 2010 draft SCP proposed regulations, a small business has 25 or less employees.³ Using the number of employees as basic classification criteria, the U.S. Small Business Administration (SBA) defines a SME to be a firm with less than 500 employees. For the purposes of this analysis, it is assumed that small enterprises have less than 20 employees, medium enterprises have between 20 and 500 employees, and large enterprises have more than 500 employees.

As shown in Table 3, small and medium enterprises are assumed to be responsible for a range of 1 to 2 chemicals of concern and therefore responsible for preparing and submitting 1 to 2 AAs. Moreover, large enterprises are assumed to be responsible for a range of 2 to 3 chemicals of concern and therefore 2 to 3 AAs. In total, it is estimated that the identified entities will need to

² For further detail on estimated costs for toxicological tests, refer to Appendix B of the report, “Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Regulations under CCR 22.”

³ Article 11 § 69311 has since been deleted from the text of proposed regulations.

prepare between 1 and 3 AAs under CCR 22, costing approximately between \$1,958 and \$45,391.

Table 3. Estimated Industry Labor Costs by Entity Size

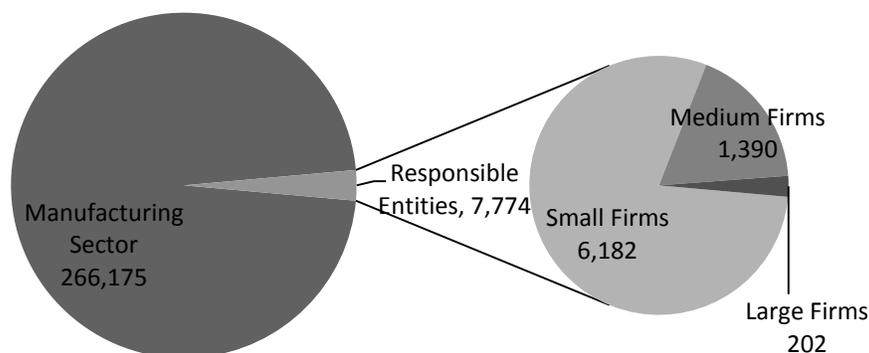
	No. of AAs	Cost
Small Enterprises		
Assuming 1 chemical per entity	1	\$1,958 – \$15,130
Medium Enterprises		
Assuming 1 to 2 chemicals per entity	1 – 2	\$1,958 – \$30,261
SMEs Subtotal	1 – 2	\$1,958 – \$30,261
Large Enterprises		
Assuming 2 to 3 chemicals per entity	2 – 3	\$3,916 – \$45,391
All Enterprises	1 – 3	\$1,958 – \$45,391

Sources: Estimated Costs of Preparation and Submission of Reproposed PMN Form (Arthur D. Little, Inc. 1979); Price Indexes for Gross Domestic Product (U.S. Department of Commerce 2012a); and ICF estimates

Responsible Entities

As shown in Figure 1, approximately 3% of firms in the manufacturing sector are estimated to be responsible entities under CCR 22. These firms include 6,182 small enterprises, 1,390 medium enterprises, and 202 large enterprises. Figure 2 shows that approximately 13% of firms in the wholesale trade sector are estimated to be responsible entities under CCR 22.⁴ These firms include 33,284 small enterprises, 6,168 medium enterprises, and 807 large enterprises.

Figure 1. Responsible Entities in the Manufacturing Sector



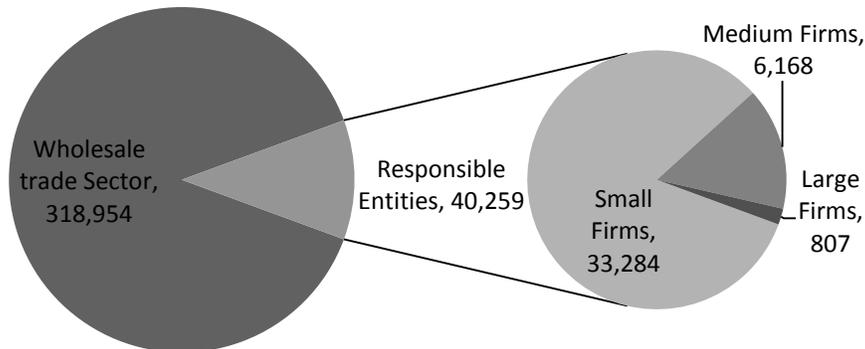
^a Assumed the CCR 22 would impact the following industries by NAICS code: 339932,

⁴ According to the U.S. Department of Commerce, the Wholesale Trade sector is comprised of establishments engaged in wholesaling merchandise, generally without transformation, and rendering services incidental to the sale of merchandise. The merchandise described in this sector includes the outputs of agriculture, mining, manufacturing, and certain information industries, such as publishing (2012b).

31522, 31523, 315291, 325612, 325611, 325510, 325620, 337122, and 337122.

Sources: U.S. Department of Commerce 2009 County Business Patterns (U.S. Department of Commerce 2009) and ICF estimates

Figure 2. Responsible Entities in the Wholesale Trade Sector



^a Assumed the CCR 22 would impact the following industries by NAICS code: 423990, 424210, 42432, 424490, 4246, and 4248.

Sources: U.S. Department of Commerce 2009 County Business Patterns (U.S. Department of Commerce 2009) and ICF estimates

References

Arthur D. Little, Inc. (1979). "Estimated Costs of Preparation and Submission of Reproposed Premanufacture Notice Form." Prepared for U.S. Environmental Protection Agency: Office of Toxic Substances. EPA Report Number: EPA 560/12-79-005. Available online at: <http://nepis.epa.gov/Adobe/PDF/91013FMB.PDF>.

U.S. Department of Commerce. (2009). United States Census Bureau: Statistics of U.S. Businesses (SUSB) Main. "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2009." Available online at: <http://www.census.gov/econ/susb/>.

U.S. Department of Commerce. (2012a). "National Income and Product Accounts Tables." Data retrieved from Table 1.1.4. Price Indexes for Gross Domestic Product. Available online at: <http://www.bea.gov/iTable/iTable.cfm?ReqID=9&step=1>.

U.S. Department of Commerce. (2012b). "2012 NAICS Definition." Sector 42 – Wholesale Trade. Available online at: [http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=42&search=2012 NAICS Search](http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=42&search=2012%20NAICS%20Search).

U.S. EPA. 1997. Appendix B: Estimating the Testing Costs. Available online at:
[http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/TS0000365E-03.pdf/\\$File/TS0000365E-03.pdf](http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/TS0000365E-03.pdf/$File/TS0000365E-03.pdf).

United States International Trade Commission (USITC). (2010). “Small and Medium-Sized Enterprises: Overview of Participation in U.S. Exports.” Investigation No.332-508. USITC Publication 4125. Available online at: <http://www.usitc.gov/publications/332/pub4125.pdf>.

**Potential Costs to the State of California
Associated with Implementing the Proposed
Safer Consumer Product Regulations
under CCR 22**

**Prepared
by
ICF International**

July 26, 2012

Table of Contents

Executive Summary	1
1. Introduction	3
1.1. Key Features of the of May 2012 Draft Regulations	4
2. Chemical of Concern and Priority Product Lists (Articles 2 and 3).....	5
2.1. Scoping Assumptions.....	5
2.2. Estimated DTSC Costs	7
3. Alternatives Assessments and Regulatory Responses (Articles 5 and 6).....	8
3.1. Scoping Assumptions.....	8
3.2. Estimated DTSC Costs	10
4. Petitions, Audits, and Confidentiality (Articles 4, 9, and 10)	11
4.1. Scoping Assumptions.....	12
4.2. Estimated DTSC Costs	13
5. Summary of DTSC Costs for Implementation of Proposed SCP Regulations	14
Appendix A: Assumptions for DTSC Government Wage	17
Appendix B: Estimated Costs Associated with Toxicological Tests for an Individual Chemical	18
Appendix C: Data Management System Development and Maintenance.....	21

Executive Summary

The following summary presents the estimated costs that would be incurred by the California Department of Toxic Substances Control (DTSC) to implement the revised draft Safer Consumer Product (SCP) regulations as published May 2012.¹ These regulations require DTSC to identify chemicals in consumer products based on potential health and environmental impacts, and to establish the regulatory responses that DTSC can take to limit exposure or reduce the level of hazard posed by these chemicals in consumer products. The following broad conclusions can be drawn from this cost analysis:

- **Annual DTSC implementation costs are estimated to range from about \$9 to \$27.2 million in the first six years, depending on the assumed scope of the SCP program.** These costs could be even higher if more chemicals in products are reviewed by DTSC, if more industry consortia or responsible entities submit Alternatives Assessment reports for review by DTSC, or if additional regulatory actions are pursued.
- **Over time, annual costs for the program are expected to increase as the cumulative number of priority chemicals and products regulated by DTSC grows.** DTSC's SCP program will be an ongoing effort to continually assess and regulate additional priority chemicals and products. Thus, as the total number of regulated chemicals and products grows, it is likely that the cumulative burden on DTSC will also trend upward over time.

The draft regulation does not specify the process and procedures that DTSC will follow to pare down the universe of chemicals into those that will be the focus of the regulatory process. In order to estimate the cost to DTSC of implementing the program, ICF has assumed that DTSC will take a number of steps to identify chemicals of concern. First we have assumed an initial "universe" of 3000 chemicals of potential interest to the DTSC. From this number we assumed that approximately 10% would be classified as chemicals of concern and that the levels of interest for this set of chemicals would be found in approximately 150 products. As noted in the draft regulation, DTSC anticipates that as many as 5 products could be considered as Priority Products in the first year of the program. ICF has assumed that once the program is fully active, an additional 6 products per year could be classified as priority across the next five years of the program. Thus, we have assumed that DTSC will need to review and assess 35 products during the first six years of the program. In addition we have assumed that the regulation will result in the formations of 100 industry consortia to generate Alternative Assessment reports and that 50% of the products identified as priority products will ultimately require regulatory determinations and/or actions by DTSC. These assumptions are presented in Table E-1.

The estimated costs to DTSC of implementing the proposed SCP regulations are shown in two ways below. Table E-2 shows DTSC costs by Article of the proposed regulation, along with additional costs that would be required to maintain the program on an ongoing basis. Table E-3 presents annual DTSC implementation costs for Year 1 through Year 6.

¹ Accessed October 25, 2010 at: http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf

Table E-1: ICF Assumptions for Implementing the May 2012 Program

Chemical and Product Assumptions	Program
Number of chemicals on “Initial Chemicals of Concern List”	3,000
Number of Priority Chemicals	300
Number of product categories listed as “under consideration”	150
Number of Priority Products identified in the first 6 years of Program	35
Alternatives Assessment and Regulatory Response Assumptions	
Number of consortia submitting AA reports	100
Percentage of priority products requiring regulatory determinations/actions	50%

Table E-2: Summary of DTSC Implementation Costs by Article

	Program
Costs by Article	
Article 2: Chemical of Concern Prioritization Process	\$25,190,000
Article 3: Product Prioritization Process	\$9,350,000
Article 4: Petition Process	\$15,000,000
Article 5: Alternatives Assessments	\$15,320,000
Article 6: Regulatory Responses	\$2,550,000
Article 9: Audits	\$360,000
Article 10: Confidentiality of Information	\$1,440,000
Additional program costs	
General program administration	\$4,860,000
Data management system development and hardware/software	\$1,700,000
Data system upkeep and management	\$2,400,000

Table E-3: Total Annual Costs across the first six years of the Program

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Program	\$19,170,000	\$14,581,667	\$9,056,667	\$27,236,667	\$14,641,667	\$9,966,667

As shown, annual costs are estimated to range from about \$9 to \$27.2 million under this Program. Thus, at the upper end of the range, DTSC’s own estimate of annual program costs of approximately \$10 to \$13 million² is a little below the cost estimates made for the newest draft regulations in this assessment, although the scope of the program DTSC estimates implementing for that cost is not known. In addition, program costs are expected to increase over time as the number of priority chemicals and products cumulates.

² See DTSC’s 45-day notice issued for the SCPA regulations, Department reference number R-2010-05.

1. Introduction

In December 2010, ICF International prepared and published an analysis of the fiscal implications that might be associated with the implementation of the Safer Consumer Product (SCP) regulations under Title 22 of the California Code of Regulations (CCR 22) titled *Potential Costs to the State of California Associated with Implementing the Proposed Safer Consumer Product Alternatives Regulations under CCR 22*.³ In (October 2011 and in) May 2012, some of the proposed requirements of the Safer Consumer Product (SCP) regulations were updated by the State of California. This paper considers these changes and represents a revision of the prior fiscal implications analysis.

The California Department of Toxic Substances Control (DTSC) is proposing the SCP regulation in order to (a) identify and prioritize chemicals or chemical ingredients in consumer products that may be considered of concern; (b) evaluate chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or reduce the level of hazard posed by priority chemicals; and (c) establish the regulatory responses that DTSC may take.

Under these regulations, DTSC would identify chemicals of concern and prioritize those chemicals based on their potential health and environmental impacts. A list of priority products containing chemicals of concern would be created as well. Product prioritization based on analyses of adverse impacts on public health and the environment would also consider implications from a life cycle perspective. Manufacturers of priority products would conduct alternative assessments to determine whether “safer”, feasible alternatives could be placed on the market. DTSC’s major responsibilities would include:

- Identifying a list of Chemicals of Concern (Article 2);
- Identifying a list of Priority Products (Article 3);
- Sharing information about Priority Chemicals and Products with manufacturers and consumers (Articles 2 and 3);
- Receiving and reviewing petitions for new Chemicals of Concern and/or Products (Article 4);
- Preparing and distributing guidance to manufacturers (in-state and out-of-state) to assist certified assessors performing Alternatives Assessments (Article 5);
- Reviewing Alternatives Assessments and determining regulatory responses (Articles 5 and 6);
- Reviewing documentation required as a result of regulatory response determinations (Article 6);
- Conducting audits of Alternative Assessments (Article 9);
- Reviewing and processing claims of confidentiality and trade secrets (Article 10); and
- Conducting general program administration.

³ Accessed October 25, 2010 at: http://www.dtsc.ca.gov/LawsRegsPolicies/upload/SCPA-Regs_APA-format-9-07-10-rev-9-12.pdf

1.1. Key Features of the of May 2012 Draft Regulations

The following provides a summary of the key features of the Revised Informal Draft 2012 regulations:⁴

- Much larger Chemicals of Concern list - The Chemicals of Concern list would consist of 3,000 Chemicals upon adoption of regulations.
- Significant Acceleration of Program –
 - The Chemicals of Concern list would take effect immediately instead of over 12 months as initially proposed.
 - Priority Products would be identified 6 months after the regulations take effect.
 - Once a product is listed on the Priority Product List, the product manufacturer has about 2 months to respond to DTSC whether it manufactures such a product or the product does not exceed threshold levels.
- Broader Scope – unlike earlier proposals, the regulations no longer limit Priority Products to children’s products, personal care products, and household cleaning products, although the Draft Regulations may prioritize listing based on these principles.⁵
- Smaller Initial Priority List – DTSC states in the May revision that initially—i.e., in the first year—it will identify no more than five Priority Products, although others can be added over time.
- Not “required” to submit CBI – The DTSC might still request confidential business information regarding certain chemical and product information, but the responsible entities would not be “required” to disclose it at the onset for the product prioritization process.
- Streamlined Alternatives Assessment – Requirements to fill-in information gaps before an Alternatives Assessment is finalized have been eliminated. Deadlines are clearly defined for the completion of preliminary and final Alternative Assessment reports.
- Exemptions - The new default *alternative analysis threshold* is 0.01% for Chemicals of Concern exhibiting nine specific hazard traits and stays the same (0.1%) for all other chemicals of concern.
- Preventing Disclosure of CBI - The current May 2012 Draft regulations still require the manufacturer or other responsible party to obtain an interim notice to prevent disclosure of a claimed trade secret if no decision is reached within a 30-day period.

This report estimates the costs to state government for establishing and implementing this new toxic substances control program, and also identifies some opportunities for mitigating these costs. Specifically, the fiscal burden associated with DTSC’s major responsibilities under Articles 2-6, 9 and 10 are estimated in this report; any state costs that might be incurred for implementation of Article 7 (Dispute Resolution) and Article 8 (Accreditation and Qualification Requirements for Performance of Alternatives Assessments) are not considered herein.⁶ Because the current proposed regulations are still somewhat vague with regard to the scope of implementation, as noted throughout this analysis, a number of assumptions were required to evaluate the burdens on government. The remainder of this

⁴ DTSC. (2011). *Safer Consumer Products --- Informal Draft Regulations: Significant Changes*. Department of Toxic Substances Control. October 31, 2011. Available online: <<http://dtsc.ca.gov/upload/SCPRegulationsInformal-DraftSignificantChanges.pdf>>

⁵ Note that the September 7, 2010 draft on which the initial (December 2010) ICF analysis was based had a broader scope similar to the current 2012 version. The November 2010 draft of the regulations narrowed the scope but the December 2010 ICF analysis did not consider this narrowing of scope in its cost analysis.

⁶ In addition, other costs, such as enforcement costs, unintended costs (e.g., litigation costs), and the potential cost to the State of California if the price of priority products purchased by the state increases as a result of the regulations, have not been included in the government cost burdens estimated in this report and could pose an additional cost for the State of California.

paper discusses the cost implications of the May 2012 draft regulation requirements for DTSC, and is organized as follows:

- Section 2 presents costs associated with implementation of Articles 2 and 3 (development of chemical and product lists);
- Section 3 addresses costs associated with implementation of Articles 5 and 6 (alternative assessments and regulatory responses);
- Section 4 estimates costs associated with implementation of Articles 4, 9, and 10 (petitions, audits, and confidentiality); and
- Section 5 presents a summary of costs estimated herein.

2. Chemical of Concern and Priority Product Lists (Articles 2 and 3)

Because the draft regulations do not specify how many chemicals and products DTSC will review or include on its “Priority” lists, broad assumptions are required regarding the scope of the program in order to conduct a cost analysis. Thus, for the purposes of this scoping analysis, assumptions were made as to how many chemicals and products will be initially reviewed and identified as “priority.” These assumptions affect the projected cost for DTSC in implementing these Articles of the SCP regulations, and thus, to the extent that the program scope is different than what is assumed herein, so too will the cost be different.

ICF’s scoping assumptions are provided in Section 2.1, followed by cost estimates in Section 2.2.

2.1. Scoping Assumptions

Assumptions about the number of chemicals and products addressed in the implementation of the SCP regulation were based on research into related programs in California and at the federal level, as well as available data on the number of consumer products in the United States.

Table 1 shows assumptions regarding the scope of the SCP regulations for the current program scope.

For the development of the initial chemical lists, ICF assumed that about 3,000 chemicals would be initially reviewed for listing.⁷ Of those chemicals under consideration, approximately ten percent were assumed to be selected as “priority chemicals.” This calculation was based on existing lists of very high concern chemicals,⁸ as well as a general assumption about the overall risk profiles of the chemicals under consideration.

For the development of the initial product lists, ICF assumed that a total of 300 consumer product categories would be initially reviewed for listing. This number is based on a review of the U.S. Census Bureau’s North American Product Classification System (NAPCS) product lists which was used to identify those product categories with consumer applications.⁹ From those product categories, around

⁷ Safer Consumer Products – Informal Draft Regulations. Significant Changes, Available online:

<http://dtsc.ca.gov/upload/SCPRegulationsInformal-DraftSignificantChanges.pdf> . Last accessed June 4, 2012.

⁸ Examples include the candidate list of Substances of Very High Concern from the European Chemicals Agency (ECHA) (http://echa.europa.eu/chem_data/authorisation_process/candidate_list_en.asp).

⁹ Products were identified by their corresponding codes under the North American Industrial Classification System (NAICS) at the six-digit level. As explained by the U.S. Census Bureau: “NAICS is a two- through six-digit hierarchical classification system, offering five levels of detail. Each digit in the code is part of a series of progressively narrower categories, and the

150 products were assumed to be listed as “products under consideration,” and then 35 products were assumed to be selected as “priority.”

Table 1. Assumptions Regarding the Scope of the SCPA Regulations

Chemical and Product Assumptions	Program
Number of chemicals on “Initial Chemicals of Concern List”	3,000
Number of Priority Chemicals	30
Number of product categories listed as “under consideration”	150
Number of Priority Products identified in the first 6 years of Program	35
Alternatives Assessment and Regulatory Response Assumptions	
Number of consortia submitting AA reports	100
Percentage of priority products requiring regulatory determinations/actions	50%

In addition to assumptions about the number of chemicals and products reviewed and listed, assumptions were also required about the effort required by DTSC staff to develop these lists.

Table 2 presents assumptions regarding the level of effort (shown in hours and full-time equivalents, or FTEs) on a “per chemical” or “per product” basis. Assumptions were developed based on the past experience of ICF toxicologists in reviewing chemical and product information. Because of the multiple components and complex manufacturing and assembly processes of many products today, a substantial effort is assumed to be required to determine whether a certain product should be listed as priority. For example, a multidisciplinary team including toxicologists, chemists, engineers, economists, and other professionals might be required to make such a determination. Further description of the effort to make a listing determination per product is provided below.

Table 2. Assumptions Regarding the Effort Required to Develop Chemical and Product Lists

	Hours	FTE
Initial Chemical List Development		
Hours <i>per chemical</i> to review technical material and determine whether to list as a “Chemical of Concern”	40	0.02
Hours <i>per chemical</i> to review technical material and determine whether to list as a “priority chemical”	60	0.04
Initial Product List Development		
Hours <i>per product</i> to review technical material and determine whether to list as a “priority product”	200	0.10
Hours <i>per product</i> to review technical material and determine whether to list as a “priority product”	500	0.24
Both Chemical and Product List Development		
Hours <i>per list</i> to solicit and respond to public comments	1041	0.50

more digits in the code signify greater classification detail. The first two digits designate the economic sector, the third digit designates the subsector, the fourth digit designates the industry group, the fifth digit designates the NAICS industry, and the sixth digit designates the national industry.” See: <http://www.census.gov/eos/www/naics/faqs/faqs.html#q5>

Figure 1. The Definition of a “Product”

The burden to DTSC of reviewing products for listing as “under consideration” and “priority” may additionally depend on the level of product the Department decides to review. For example, using a six-digit NAICS/NAPCS level product definition means that DTSC would have to review multiple consumer product types to list one six-digit NAICS/NAPCS product.* As an example, the product category “Toilet Preparation Manufacturing” (NAICS/NAPCS No. 325620) includes:

- Shaving preparations
- Perfumes, toilet waters, and colognes
- Shampoos
- Hair and scalp conditioners
- Hair creams, pomades, sprays, and rinses
- Hair mousse, perms, and coloring preparations
- Creams, lotions, and oils
- Dentifrices, mouthwashes, gargles, and rinses
- Other cosmetics and toilet preparations

2.2. Estimated DTSC Costs

FTE costs associated with the listing of chemicals and products of concern are estimated below. These program costs are assumed to be experienced between January of the first year and December of the third year, according to the proposed schedule. This analysis assumes that DTSC will rely primarily on public information and data submitted by manufacturers to make its listing determinations, and thus, that DTSC does not incur extramural costs for the generation of toxicity test data, such as tests for acute and chronic toxicity, developmental/reproductive toxicity, mutagenicity, and ecotoxicity. Such testing can be costly, as described in Appendix B.

Table 3 below presents the estimated FTE costs associated with DTSC’s implementation of Articles 2 and 3 of the proposed SCPA regulations.

Table 3. Estimates of Program FTEs and Associated Cost for Articles 2 and 3

	Program	
	FTE	Cost*
Article 2: Chemical Prioritization Process		
Develop initial list of Chemicals of Concern	57.7	\$10,010,000
Solicit and respond to public comments; finalize list of Chemicals of Concern	0.5	\$90,000
Develop initial list of Priority Chemicals	86.5	\$15,010,000
Solicit and respond to public comments; finalize list of Priority Chemicals	0.5	\$90,000
Article 2 Subtotal	145.2	\$25,190,000
Develop initial list of Priority Products	28.8	\$5,000,000
Solicit and respond to public comments; finalize list of Priority Products	0.5	\$90,000
Develop initial list of Priority Products	24.0	\$4,170,000
Solicit and respond to public comments; finalize list of Priority Products	0.5	\$90,000
Article 3 Subtotal	53.9	\$9,350,000
INITIAL LIST DEVELOPMENT TOTAL	199.1	\$34,530,000

Totals may not sum due to independent rounding.

* Assumptions regarding the average cost per FTE are described in Appendix A.

† Article 3 total does not include costs associated with the receipt and review of priority product notification reports.

3. Alternatives Assessments and Regulatory Responses (Articles 5 and 6)

As noted previously, because the draft regulations do not specify how many chemicals and products DTSC will include on its “Priority” lists beyond the first year, it is not possible to know precisely how many businesses will be affected. Thus, in order to conduct a cost analysis, broad assumptions are required regarding the scope of affected businesses. For the purposes of this scoping analysis, assumptions were made as to how many businesses/consortia will be required to submit notifications, perform alternative assessments, and be subject to regulatory responses. These assumptions affect the overall projected cost for the DTSC in implementing the proposed SCP regulations, and thus, to the extent that the number of affected businesses is different than what is assumed here, so too will the cost be different.

ICF’s scoping assumptions are provided in Section 3.1, followed by cost estimates in Section 3.2.

3.1. Scoping Assumptions

Assumptions about the number of reports that DTSC would receive and review were based on available data on the number of consumer products and associated manufacturers in the United States, as well as ICF estimates. Reports, such as Alternatives Assessments (AAs), must be submitted by “responsible entities,” which are defined under the proposed SCP regulations to include manufacturers, importers, distributors, retailers or any other entity that has a contract with an importer, distributor, or retailer. Although responsible entities up and down the supply chain will be subject to the proposed requirements, businesses are allowed to meet the requirements through consortia such as trade associations, partnerships, and other similar arrangements. Thus, for the purposes of this report, it is assumed that two consortia will submit AAs per priority product, with each AA representing a

compilation of information from affected businesses belonging to those consortia.¹⁰

Table 4 shows flow-down assumptions regarding the number of reports received by DTSC under the May 2012 SCP proposed regulation. In addition to assumptions about the number of AA reports submitted and the number of regulatory determinations, assumptions were also required about the effort required by DTSC staff to review these reports and make these determinations.

Table 4. Key Assumptions Regarding the Number of Reports Received and Regulatory Responses Required by the Proposed SCP Regulation

	Program
Alternatives Assessment Assumptions	
Number of consortia submitting notifications and AA reports	40
Percentage of manufacturers submitting <i>alternatives analysis threshold</i> exemption requests	10%
Regulatory Response Assumptions	
Percentage of priority products requiring regulatory determinations/actions	50%
Percentage of manufacturers producing priority products subject to regulatory response requirements	50%

Table 5 presents assumptions regarding the level of effort (in hours and FTEs) on a per report or per regulatory determination basis. Assumptions were developed based on expert input and existing burden estimates for federal chemical programs with some similar components (EPA’s TSCA Inventory Update Reporting [IUR]¹¹ and Significant New Use Rules [SNURs]¹²). It might be expected that costs will decrease because of economies of scale and build up of organizational knowledge over time; however, for this analysis costs are assumed to be constant over the timeframe consider by this report.

¹⁰ It is likely that many more businesses will be impacted in a myriad of ways by these proposed regulations. For the purposes of estimating costs to DTSC, however, it was only necessary to determine the number of businesses that might be submitting reports, notifications, or requests to DTSC, and thus the number of such documents that DTSC must review and process.

¹¹ EPA. (1999). Economic Analysis of Proposed Amendments to the TSCA Section 8 Inventory Update Rule. March 1, 1999.

¹² EPA. (2008). Information Collection Request, TSCA Section 5(a)(2) Significant New Use Rules for Existing Chemicals. EPA ICR No. 1188.08; OMB Control No. 2070-0038.

Table 5. Key Assumptions Regarding the Level of Effort Required to Review Reports and Make Regulatory Determinations

	Hours	FTEs
Alternatives Assessment		
Hours to prepare guidance materials to assist persons in performing AAs	1,040	0.50
Hours <i>per report</i> to review AA notification report and Preliminary AA report	20	0.01
Hours <i>per report</i> to review AA Work Plans	20	0.01
Hours <i>per detailed (final) report</i> to review and issue notice of completion or deficiency	1,000	0.48
Hours <i>per detailed (final) report</i> to review revised report	40	0.02
Hours <i>per detailed (final) report</i> to determine if regulatory response is required	40	0.02
Hours <i>per request</i> to review <i>alternatives analysis threshold</i> exemption requests	40	0.02
Regulatory Responses		
Hours <i>per product</i> to determine regulatory response*	700	0.34
Hours <i>per report</i> to review additional data requested for evaluation of AA Reports	20	0.01
Hours <i>per report</i> to review End-of-Life Management reports	20	0.01
Hours <i>per request</i> to review exemption submissions from regulatory response requirements and issue notice of grant/deny	40	0.02
Hours <i>per report</i> to review notification reports from responsible entities of applicability and completion of regulatory response	220	0.11
Hours <i>per year</i> to develop and update quarterly a Regulatory Response Report	350	0.17

* This includes requests for any supplemental information, making the appropriate regulatory determination, soliciting and responding to comments on the proposed regulatory response, and finalization and notice of the final determination.

3.2. Estimated DTSC Costs

This section presents estimated costs to DTSC associated with the receipt and review of AA reports and related documentation (such as exemption requests), as well as the burden associated with making regulatory determinations and reviewing related documentation (such as required reports, exemption requests, comments, status updates and other types of documents).

Several important limitations must be noted. First, these costs are highly variable depending on the number of alternative assessments received and the number and type of regulatory determinations that DTSC decides to make. While broad assumptions have been made to this effect, the scope of the implementation of these Articles is uncertain, and thus costs could be substantially different than what are estimated here if the extent of implementation is also different.

Second, although there is an estimated time frame from the first notification through the completion of the AA, uncertainty remains high in terms of the time involved in reviewing and oversight of the regulatory responses. Thus, the timeframe for incurring these costs is uncertain. Preliminary AA reports are due 180 days after the priority product is listed or 120 days from when the Work Plans are due. However, extensions of up to 90 days may be requested and granted under special circumstances. Based on the proposed regulations, it might reasonably be assumed that preliminary AA Reports largely will be submitted by 6 months and final AA reports within one to two years (by 18 months and not to exceed 30 months) following DTSC’s approval of the preliminary report. It is also not known how long after the submission of the AA Reports regulatory responses will be determined, though the Department will be required to issue a notice of compliance, disapproval or ongoing review within 60 days after

submission of the final AA report. Thus, it is difficult to attribute the costs to DTSC of reviewing AA Reports and making regulatory response determinations to individual years. That said, the finalization of an initial priority product list—and the assumption that about 35 products will be on it by the end of the sixth year—has the potential to require a substantial number of AA Reports and associated regulatory responses in the timeframe of about two years following the publication of the priority product list.

Table 6 below presents the estimated FTE costs associated with DTSC’s implementation of Articles 5 and 6 of the proposed SCPA regulations. As mentioned above, the majority of these costs are assumed to be incurred in the two years following the publication of the initial priority product list; costs estimated below are not annual costs. Program costs by year are estimated in Section 5 of this report.

Table 6. Estimates of Program FTEs and Associated Cost for Articles 5 and 6

	Program	
	FTE	Cost*
Article 5: Alternative Assessments		
Prepare guidance materials to assist persons in performing AAs	0.5	\$90,000
Review AA Work Plans	0.7	\$120,000
Review notification and Preliminary AA reports	0.7	\$120,000
Review <i>alternative analysis threshold</i> exemption requests	17.6	\$3,050,000
Review Final AA reports	68.9	\$11,950,000
Article 5 Subtotal	88.4	\$15,320,000
Article 6: Regulatory Responses		
Prepare regulatory response determination	5.9	\$1,020,000
Review reports and additional information required by regulatory determinations	0.2	\$40,000
Review exemption requests	0.1	\$20,000
Review notification reports on applicability and completion of regulatory responses	8.4	\$1,460,000
Develop annual Regulatory Response Report	0.0	\$10,000
Article 6 Subtotal	14.7	\$2,550,000
ARTICLE 5 & 6 TOTAL	103.0	\$17,870,000

Totals may not sum due to independent rounding.

* Assumptions regarding the average cost per FTE are described in Appendix A.

4. Petitions, Audits, and Confidentiality (Articles 4, 9, and 10)

This section estimates the annual burden to DTSC associated with petitions, audits, and requests for confidentiality under the proposed SCP regulations. Article 4 of the SCP regulations allows for any person to petition DTSC in order to evaluate chemicals or products for inclusion in or removal from the program, while Article 9 enables DTSC to perform audits on, but is not limited to, AAs, AA Reports, information related to notifications and implementation of regulatory responses. Article 10 allows any person to submit information confidentially to DTSC. The assumptions used affect the estimated cost of the program and thus, the costs of the program will vary depending on the difference in scope from those assumptions stated below.

ICF’s scoping assumptions are provided in Section 4.1, followed by cost estimates in Section 4.2.

4.1. Scoping Assumptions

Assumptions were used to determine the number of petitions and audits processed annually, as well as the number of confidentiality claims that would accompany report submissions. These assumptions were based upon knowledge of similar processes and expected involvement of the public and manufacturers regulated under the program. Table 7 lists the assumptions used for this section. Based upon the resources required to perform an audit and the logistics involved, a small number of audits are expected to be performed each year by DTSC. ICF also assumed that all reporting parties will choose to divulge their chemicals under a confidential or trade-secret agreement due to the intellectual property nature of consumer products. This assumption is consistent with EPA estimates that about 95% of pre-manufacture notices for new chemicals contain information that is claimed as confidential.¹³ It is also expected that a significant number of requests for information under the California Public Records Act (CPRA) will be received, as many as 50 per year, using the number of federal Freedom of Information Act (FOIA) requests for Region 9 (which includes California) as a guide.¹⁴

Table 7. Assumptions about Number of Petitions, Audits, and Confidential Requests

	Program
Petition Process	
Number of petitions received per year for the 6 years assessed herein	150
Percentage of petitions granted	50%
Audits	
Number of reports audited each year	7
Confidentiality of Information	
Percentage of affected businesses submitting claims of confidentiality or trade secrets	100%
Number of requests under CPRA received per year	50

By expanding upon the assumptions about the number of processes expected, assumptions were made about the level of effort required by DTSC staff to complete these tasks.

Table 8 presents assumptions regarding the level of effort (shown in hours and full-time equivalents, or FTEs) on a per task basis for Articles 4, 9, and 10 of the proposed regulations. Assumptions were developed based on expert input.

¹³ EPA. (2006). U.S. Government Accountability Office, Testimony before the Committee on Environment and Public Works, U.S. Senate, Chemical Regulation, Actions Are Needed to Improve the Effectiveness of EPA’s Chemical Review Program. Statement of John B. Stephenson, Director, Natural Resources and Environment. GA-06-1032T. Available online at: <http://www.gao.gov/new.items/d061032t.pdf>

¹⁴ Nearly 600 FOIA requests were received in 2009 for Region 9, which includes California as well as Arizona, Hawaii, Nevada, American Samoa, and Guam (<http://www.epa.gov/foia/docs/2009report.pdf>). Substantially fewer CPRA requests are assumed be received in California related to this rulemaking.

Table 8. Assumptions Regarding the Level of Effort Required for Handling Petition Process, Audits, and Reviewing of Confidentiality Requests

	Hours	FTE
Petition Process		
Hours <i>per petition</i> to prioritize, conduct technical review, request additional information, and prepare notification	120	0.06
If petition is granted, hours <i>per chemical or product</i> to add and prioritize chemical and/or product according to Articles 2 and 3	200	0.1
Audits		
Hours <i>per audit</i> to audit preliminary and final AA reports and issue notification of findings	100	0.05
Confidentiality of Information		
Hours <i>per claim</i> to review claims of confidentiality	40	0.02
Hours <i>per claim</i> to review claims of trade secret protection	40	0.02
Hours <i>per request</i> to notify submitters of requests under the California Public Records Act	1	< 0.01

4.2. Estimated DTSC Costs

Costs associated with the petition and audit processes, as well as the handling of confidential information are estimated below. These costs are assumed to be experienced annually for the duration of the program as it continues and expands in scope to accommodate more chemicals, potentially increasing in the out-years as the number of priority chemicals and products also increases.

Table 9 below presents the estimated FTE costs associated with DTSC’s implementation of Articles 4, 9, and 10 of the proposed SCPA regulations.

Table 9. Estimates of Program FTEs and Associated Annual Cost for Articles 4, 9 and 10

	Program	
	FTE	Cost*
Article 4: Petition Process		
Review, prioritize, and conduct technical reviews for petitions received (annually)	7.2	\$1,250,000
Add and prioritize chemicals and products to listings subject to Articles 2 and 3 (annually)	7.2	\$1,250,000
Article 4 Subtotal	14.4	\$2,500,000
Article 9: Audits		
Audit Preliminary and Final AA and issue findings (annually)	0.3	\$60,000
Article 10: Confidentiality of Information		
Review and respond to claims of confidentiality, trade secret, and requests under CPRA (annually)	1.4	\$240,000

Totals may not sum due to independent rounding.

* Assumptions regarding the average cost per FTE are described in Appendix A.

5. Summary of DTSC Costs for Implementation of Proposed SCP Regulations

The proposed SCP regulations include initial activities to get the program up-and-running, and ongoing activities to support the program's goals, as described in the sections above. This section summarizes those costs and organizes them by the years in which they are assumed to be incurred.

This analysis has attempted to estimate the major costs to DTSC associated with implementation of the proposed SCP regulations. In addition to those costs estimated in previous sections of the report for each Article of the regulation, other costs will also be incurred related to general program administration, such as posting documentation on DTSC's website or evaluating deadline extension requests, and is assumed to be managed annually by six FTEs. Likewise, the creation of a data management system is expected to be required to handle the large amount of data and reports that will be gathered and submitted under these proposed regulations. Appendix C presents the assumptions related to the cost of developing and maintaining a data management system.

These costs are summarized in Table 10 and Table 11 below. In Table 10, costs are totaled per Article and additional program cost category; because some costs are one-time while other costs will be incurred annually, program costs are not summed in this table. In Table 11, costs are distributed annually over the first six years of the program. For example, the initial chemical listing process described in Article 2 is assumed to occur in the first and fourth year of the program, and hence those costs have been divided between year 1 and year 4. Likewise, the review of AA reports and initiation of associated regulatory responses is expected to take place in the two years following the publication of the priority product list, and thus those costs are divided among the first two years. Other costs are experienced annually—such as the petition and auditing processes. Table 11 presents assumptions for the years in which each cost will be incurred.¹⁵

As shown, annual costs are estimated to range from about \$9.3 to \$34.4 million under the scope of the May 2012 Informal Draft Regulation. Thus, at the upper end of the range, DTSC's estimate of annual program costs of approximately \$10 to \$13 million¹⁶ is on the lower bound of the cost estimates made in this assessment, although the scope of the program DTSC estimates implementing for that cost is not currently known. However, the scope might be revealed if DTSC releases an economic analysis with the formal release of the draft regulation. In addition, program costs are expected to increase in the out-years as the number of priority chemicals and products cumulates and decrease slightly because of efficiencies of scale.

The following broad conclusions are drawn from this cost analysis:

- **Annual DTSC implementation costs are estimated to range from about \$9 to \$27.2 million in the first six years, depending on the assumed scope of the SCP program.** These costs could be even higher if more chemicals or products are reviewed by DTSC, if more industry consortia submit AA Reports for review by DTSC, or if additional regulatory actions are pursued. Conversely these costs would reduce if the scope of the program is narrowed.

¹⁵ This assumes that the list of priority products is revised per the minimum stated requirement of at least once every three years.

¹⁶ See DTSC's 45-day notice issued for the SCPA regulations, Department reference number R-2010-05.

- **Annual costs over time for the program are expected to increase as the cumulative number of priority chemicals and products regulated by DTSC also grows.** DTSC’s SCP program will be an ongoing effort to continually assess and regulate additional priority chemicals and products. Thus, DTSC is expected to continue to review and list new chemicals and products, and thus new AA reports will be generated and new regulatory responses will be pursued. As the total number of regulated chemicals and products grows, it is likely that the cumulative burden on DTSC will also trend upward in the out-years beyond the scope of this analysis.

Table 10: Summary of DTSC Implementation Costs by Article

	Program	
	Total FTE	Total Cost
FTE costs by Article		
Article 2: Chemical Prioritization Process	145.2	\$25,190,000
Article 3: Product Prioritization Process	53.9	\$9,350,000
Article 4: Petition Process	14.4	\$15,000,000
Article 5: Alternatives Assessments	88.4	\$15,320,000
Article 6: Regulatory Responses	14.7	\$2,550,000
Article 9: Audits	0.3	\$360,000
Article 10: Confidentiality of Information	1.4	\$1,440,000
Additional program costs		
General program administration	6.0	\$4,860,000
Data management system development and hardware/software*	--	\$1,700,000
Data system upkeep and management*	--	\$2,400,000

* See Appendix C for estimation of data management system costs.

Table 11: Summary of DTSC Implementation Costs by Year Incurred under this Program

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
FTE costs by Article:						
Article 2: Chemical Prioritization Process	\$12,595,000			\$12,595,000		
Article 3: Product Prioritization Process	\$4,675,000	\$4,675,000		\$4,675,000	\$4,675,000	
Article 4: Petition Process (Annual)		\$2,500,000	\$2,500,000	\$2,500,000	\$2,500,000	\$2,500,000
Article 5: Alternatives Assessments		\$5,106,667	\$5,106,667	\$5,106,667	\$5,106,667	\$5,106,667
Article 6: Regulatory Responses				\$850,000	\$850,000	\$850,000
Article 9: Audits (Annual)					\$60,000	\$60,000
Article 10: Confidentiality of Information	\$240,000	\$240,000	\$240,000	\$240,000	\$240,000	\$240,000
Additional program costs:						
General program administration (Annual)	\$810,000	\$810,000	\$810,000	\$810,000	\$810,000	\$810,000
Data management system development & hardware/software	\$850,000	\$850,000				
Data system upkeep and management (Annual)		\$400,000	\$400,000	\$400,000	\$400,000	\$400,000
TOTAL ANNUAL COSTS						
Annual Costs	\$19,170,000	\$14,581,667	\$9,056,667	\$27,236,667	\$14,641,667	\$9,966,667

Appendix A: Assumptions for DTSC Government Wage

Four employee categories of labor (junior staff analyst, associate staff analyst, manager, and senior manager) were used in this cost analysis. Rates were assigned based upon position salaries listed in the 54th edition of the California State Civil Service Pay Scales. It should be noted, however, that a number of other specialists from other professional fields are also likely to be engaged in carrying out some portion of the tasks associated with DTSC’s administration of the regulation. For purposes of assessing the costs for this program we have constrained the number of labor categories to the four identified above under the assumption that the range of costs associated with these four categories will be representative of labor costs for other personnel that might be involved with the regulatory process. An overall level of effort was determined for each activity, and a set percentage of that LOE assumed to be performed by each labor category (i.e., 30% by junior staff, 40% by associate staff, 20% by managers, and 10% by senior managers), as shown in Table 12 below.

The average hourly wages were derived from the California pay scales for employees as determined by the Department of Personnel Administration¹⁷ and include a multiplier factor of 2.1 applied for overhead and benefits, as recommended by EPA in Assessment of Compliance Assistance Projects Compliance Information Collection Requests (ICRs).¹⁸ These wages are shown in Table 12.

Table 12. Government Labor Costs Used in the Cost Analysis

Labor Category	Employee Category	Percentage of LOE	Hourly Wage Rate (loaded)	Cost per FTE
Junior Staff Analyst	JY25	30%	\$39.54	\$82,249
Associate Staff Analyst	JY35	40%	\$59.05	\$122,828
Manager	BH80	20%	\$88.39	\$183,849
Senior Manager	BH76	10%	\$102.00	\$212,154
Weighted Average			\$63.36	\$131,791

¹⁷ California State Civil Service Pay Scales - Online Manual 54th Edition. CA Department of Personnel Management. 2010. Available online at: < <http://www.dpa.ca.gov/publications/pay-scales/index.htm> >.

¹⁸ Information Collection Request for Assessment of Compliance Assistance Projects. EPA. Available online at: <<http://www.epa.gov/oecaerth/resources/publications/assistance/asures/generic-icr-186003.pdf>>

Appendix B: Estimated Costs Associated with Toxicological Tests for an Individual Chemical

While DTSC is assumed to incur no extramural costs for the generation of toxicity test data, to the extent that such test data is required to make listing determinations, the generation of that data could be costly for responsible entities and/or chemical manufacturers who would be involved in developing the information for DTSC use.

The cost of testing for just a single chemical can be substantial. Although the 1998 EPA study estimated the cost of a basic set of test data at approximately \$200,000 per chemical,¹⁹ information from other sources—including from testing laboratories and other studies—suggests that those costs can be significantly higher. Table 13 below summarizes these potential testing costs.

Table 13. Range of Toxicological Test Costs for an Individual Chemical

Test Type	Description/ Comments	Associated Costs *
Mandatory Tests under SB 578 §25432		
Carcinogenicity	<p><u>Test Protocol:</u> This test requires the review of 40 tissues plus lesions/tumors</p> <p><u>Animal Testing Burden:</u> Test protocol requires the use of 1000 rodents (2 sexes per species, 2 species, 500 animals per species)</p> <p><u>Cost Considerations:</u> The low end of the cost range would be highly unlikely. Any result of toxicological significance requires more detailed pathology which will increase the cost. The choice of rat species will affect the cost—Charles River rats are more expensive than Fischer rats because they must be housed individually.</p>	\$1.1 million (for a mouse study) to ~\$5 million
Reproductive Toxicity	<p><u>Test Protocol:</u> EPA Protocol 870.3800</p> <ul style="list-style-type: none"> • 2-generation rodent reproduction study <p><u>Animal Testing Burden:</u></p> <ul style="list-style-type: none"> • 1800 laboratory rats (parental = 20 males with 20 dams per dose group = 40 * 4 dose groups = 160 rats) • Each rat will litter about 10 pups (800 pups = F1 generation). F1 breeding = 1 male * 1 female per litter = 80 * 10 = 800 pups in the F2 generation. 	\$700,000 to \$1,000,000
Tests That Could Be Required If Determined to be Technically Feasible Under SB 578 §25433		
Developmental Toxicity	<p><u>Test Protocol:</u> EPA Protocol 870.3700</p> <p><u>Animal Testing Burden:</u></p> <ul style="list-style-type: none"> • Test protocol requires 2 species of lab animals (rodents and rabbits) • 1600 laboratory animals per substance (20 pregnant dams per dose group, 4 dose groups total * 2 species = 160 dams) • Each rat will litter about 10 pups (800 pups); each rabbit will litter about 8 offspring (640 offspring) 	\$250,000 to \$300,000

¹⁹ The set of testing data assumed here is based on those tests required by the Organization for Economic Cooperation and Development's Screening Information Data Set (OECD/SIDS) program: acute toxicity; chronic toxicity; developmental/reproductive toxicity; mutagenicity; ecotoxicity and environmental fate.

Test Type	Description/ Comments	Associated Costs*
	<u>Cost Considerations:</u> <ul style="list-style-type: none"> The rabbit study will be more expensive because they require larger inhalation chambers 	
Neurotoxicity	<u>Test Protocol:</u> EPA Protocol 870.6200 (Neurotoxicity screening battery) <u>Animal Testing Burden:</u> <ul style="list-style-type: none"> Neurotoxicity screening battery requires 80 – 120 laboratory rats (10-15 per sex per dose group; 3 doses + control group) <u>Test Protocol:</u> EPA Protocol 870.6300 <ul style="list-style-type: none"> Developmental neurotoxicity study <u>Animal Testing Burden:</u> <ul style="list-style-type: none"> 1300 – 1600 laboratory rats 	\$700,000 to \$1,000,000
Immunotoxicity	<u>Test Protocol:</u> No standard protocol for immunotoxicity testing is in use.	~\$86,000
Endocrine Screening	<u>Test Protocol:</u> No standard protocol for endocrine screening is in use. <ul style="list-style-type: none"> EDSP Tier I screening assays include: <ul style="list-style-type: none"> Uterotrophic (24 rats) Male pubertal (45 rats) Hershberger (24 rats) ER/AR binding Adult male (60 rats) Steroidogenesis Aromatase Amphibian metamorphosis Female pubertal (4 rats) Fish screen <u>Cost Considerations:</u> <ul style="list-style-type: none"> Because there is no standard protocol for endocrine screening, it is possible that the costs of these tests could be much higher. 	\$400,000 to \$1,000,000
Respiratory Toxicity	<u>Test Protocol:</u> No standard protocol for respiratory toxicity is in use.	\$82,000
Tests More Typically Conducted on Chemicals in Production		
Acute Oral Toxicity	<u>Test Protocol:</u> LD50 test, OPPTS 870.1100 <ul style="list-style-type: none"> Test evaluates the dose at which 50% of the test population dies Clinical observations, body weights, food consumption, clinical pathology, gross pathology, histopathology (30 tissues plus lesions) <u>Animal Testing Burden:</u> <ul style="list-style-type: none"> 40 laboratory rats (4 groups, 5 rats per sex per group) 	\$4,000 to \$32,000
Acute Inhalation Toxicity with Histopathology	<u>Test Protocol:</u> <ul style="list-style-type: none"> In this test, the highest dose is given to determine how many 	\$25,000

Test Type	Description/ Comments	Associated Costs*
	animals die. <ul style="list-style-type: none"> Tissues are cut, but they are not evaluated. 	
90-day Subchronic Oral Toxicity	<u>Test Protocol:</u> OECD 408, OPPTS 870.3100 <ul style="list-style-type: none"> Clinical observations, body weights, food consumption, clinical pathology, FOBs, urinalysis, gross pathology, histopathology (40 tissues plus lesions) <u>Animal Testing Burden:</u> <ul style="list-style-type: none"> 80 laboratory rats (4 groups, 10 rats per sex per group) 	\$150,000 to \$200,000
2-year Chronic Oral Toxicity	<u>Test Protocol:</u> OECD 452 <ul style="list-style-type: none"> Clinical observations, body weights, food consumption, clinical pathology, urinalysis, gross pathology, histopathology (50 tissues plus lesions/tumors) <u>Animal Testing Burden:</u> <ul style="list-style-type: none"> 160 laboratory rats (4 groups, 20 rats per sex per group) <u>Cost Considerations:</u> <ul style="list-style-type: none"> A 2 year chronic inhalation toxicity study would be twice as expensive as the chronic oral toxicity study because it is time- and labor-intensive to move the animals in and out of the inhalation chamber each day (or 5 out of 7 days per week) 	\$750,000 to \$1 million
Mutagenicity Screen	<u>Test Protocol:</u> This study is done to indicate whether further carcinogenicity testing is needed.	\$4,000 to \$6,000

* Costs are based on: (a) estimates received from the following testing laboratories— Alberta Research Council, Best American Toxicology Testing Services, IIT Research Institute, and Toxicon Corporation—which were contacted between May 24, 2007 and June 12, 2007; (b) responses from ACC members (May & June, 2007 and July 13, 2012); and (c) estimates from Becker (2007), Crofton (2006), EPA (1997), NIEHS (1997), and Belzer (2009).

References:

Becker, Rick. 2007. Comments on Costs and Animal Welfare Impacts of Toxicity Testing Requirements of SB 578.

Belzer, Richard B. 2009. An Analysis of EPA’s Information Collection Request Seeking OMB Approval to Impose Mandatory Tier 1 Assay Testing in Support of the Endocrine Disruptor Screening Program. May 21.

Crofton, Kevin. 2006. Developmental Neurotoxicity Testing: The Challenge. March 13. Available at <[http://caat.jhsph.edu/programs/workshops/testsmart/dnt/proceedings/2_Crofton.ppt#274,6,Current Testing Approach versus Reality](http://caat.jhsph.edu/programs/workshops/testsmart/dnt/proceedings/2_Crofton.ppt#274,6,Current%20Testing%20Approach%20versus%20Reality)>.

NIEHS. 1997. Health Agencies, Regulated Industry Agree to Seek New, Faster Standard Animal Test for Cancer-Causing Chemicals. February 27. Available at <<http://www.hhs.gov/news/press/1996pres/960227.html>>.

U.S. EPA. 1997. Appendix B: Estimating the Testing Costs. Available at <[http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/TS0000365E-03.pdf/\\$File/TS0000365E-03.pdf](http://yosemite.epa.gov/ee/epa/riafile.nsf/vwAN/TS0000365E-03.pdf/$File/TS0000365E-03.pdf)>.

Appendix C: Data Management System Development and Maintenance

DTSC will receive and manage data, notifications, requests, and reports from businesses related to listed chemicals and products from potentially tens of thousands of businesses. It is not clear whether DTSC will accept electronic submissions (e.g., through a Web site), although it is likely that such a system would be an efficient selection. At a minimum, DTSC will need a data management system that can perform basic functions, including tracking receipt of information from industry, maintenance and management of data, and searching and reporting. For example, in order to review the data submissions, DTSC staff may need to query the database to aggregate data by chemical, or to search for all products of a certain type that contain priority chemicals. In developing the system, special provisions for dealing with and protecting confidential business information will need to be developed, as will an interface for information made publicly available.

Table 14 presents the estimated cost of developing such a data management system. As shown, development costs, including systems development and guidance documentation development, represent the large majority of the cost of a data management system. Hardware and third party software costs are estimated in the range of \$100,000 to \$300,000 for an electronic submission receiving system alone. A total one-time cost of approximately \$800,000 to \$1,700,000 is consistent with costs of developing similar systems for State-level EPAs in the past, which have typically ranged from \$1 to \$10 million, with maintenance costs of up to \$5 million annually depending on the evolution of system requirements and the costs to cleanse and manage the data. The annual costs of maintaining the data management system are estimated to range from \$100,000 to \$300,000, depending on the level of maintenance required. The lower bound estimate includes only base costs to keep the system running and fix bugs; the upper bound estimate would cover adding new functionality and operations activities (such as hosting).²⁰

Table 14. Estimated Total One-Time and Annual Cost of Developing a Data Management System

Data Management System Task	Range of Costs
Development, including: Systems analysis and design Systems development (e.g. of electronic reporting forms, user interfaces for electronic data submission, and functionality) Systems testing Guidance documentation development	\$700,000 - \$1,400,000
Acquiring and setting up hardware and software	\$100,000 - \$300,000
Total Set-up Costs	\$800,000 - \$1,700,000
Maintenance	\$100,000 - \$400,000

²⁰ These costs are also consistent with those estimated by DTSC for the development of a Toxics Information Clearinghouse (TIC), as mandated by Health and Safety Code Section 25256; a feasibility study report estimated approximately \$1.1 million in one-time development costs, plus about \$400,000 in continuing costs.²⁰ The TIC would provide a Web-based system for collecting, maintaining, and distributing chemical hazard trait and environmental and toxicological end-point data.



MICHAEL P. WALLS
VICE PRESIDENT
REGULATORY & TECHNICAL AFFAIRS

October 11, 2012

United States
US – TBT Enquiry Point
Washington, D.C.
Submitted via email to: ncsci@nist.gov

RE: TBT Notification G/TBT/N/USA/727 – Proposed California Department of Toxic Substances Control “Safer Consumer Product Regulation”

Dear Sir or Madam:

The American Chemistry Council (ACC) believes that the California Department of Toxic Substances Control’s (DTSC) proposed Safer Consumer Product Regulation, notified to the World Trade Organization’s (WTO) Technical Barriers to Trade Committee, August 8, 2012, raises several significant concerns about conformance with WTO obligations and its potential impact on global trade. ACC hopes that these comments will prompt DTSC to reevaluate key elements of the regulatory proposal, maintaining a framework that is protective of human health and the environment while avoiding adverse trade and negative competitive impacts.

ACC is most concerned with the potential trade implications of three elements of the proposed regulation:

- The complexity, scope and likely burden of the draft stand at odds with federal U.S. efforts to reduce regulatory burdens.
- The Priority Product identification, Alternatives Analysis Threshold, and alternatives assessment accreditation and certification may well be inconsistent with Article 2.2 of the Agreement on Technical Barriers to Trade (TBT Agreement).
- The proposed disclosure of trade secrets, for instance chemical identity, may violate Article 39.1 and 39.2 of the Agreement on Trade Related Intellectual Property (TRIPS).

Counter to U.S. Efforts to Reduce Regulatory Burdens and Provide Clarity

The United States is committed to improving regulation and regulatory review, as evidenced by Executive Order (E.O.) 13563, signed by the President, January 18, 2011. E.O. 13563 complements a 1993 E.O. titled, “Regulatory Planning and Review,” stating that the U.S. regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. It also must do the following: promote predictability and reduce uncertainty; identify and use the least burdensome and most innovative tools for achieving regulatory goals; take into account qualitative and



quantitative benefits and costs; and, ensure regulations are accessible, consistent and written in an understandable manner. The proposed California regulation fails to take into consideration or address a number of the aforementioned elements.

The Economic and Fiscal Impact Statement completed by DTSC is indicative of the lack of certainty provided by the proposed regulation.¹ Although the form notes that this regulation will impact businesses and/or employees, small businesses, jobs or occupations and California competitiveness, it does not offer any quantitative figures related to these impacts. For example, the total number of affected businesses and statewide dollar costs are listed as “unknown.”

A second example is California DTSC’s proposed unique process to establish the “Alternatives Analysis Threshold” level, or *de minimis* level. The Alternatives Analysis Threshold neither follows the precedent set by the Globally Harmonized System (GHS) for Classification and Labeling, nor the precedent set by the European Union’s REACH program. A *de minimis* threshold of 0.1% is essential to identifying and prioritizing the products containing chemicals of legitimate concern, that have potentially harmful exposures. From a technical perspective, 0.1% is the most practical threshold level that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. In addition to GHS classification and REACH, a number of other standards and regulatory programs defer to the internationally accepted level of 0.1% (e.g., the Consumer Product Safety Commission, and Europe’s Classification, Labeling and Packing (CLP) Regulation), thus millions of dollars are invested in compliance at this level on a global scale. This may be in conflict with Articles 2.6 and 2.7 of the TBT Agreement.

Proposed Regulation Will Likely Create Unnecessary Obstacles to International Trade

DTSC’s regulatory proposal could affect nearly every product sold in the State of California, with subsequent impacts on the U.S. market as well as abroad. The scope of the program, largely dictated by the California Health and Safety Code’s definition of “consumer product”² is broad. The proposed regulation establishes unique criteria for the identification and prioritization of “Chemicals of Concern” and “Priority Products”. It also establishes a unique set of requirements for conducting an alternatives assessment, as well as who may perform such an assessment. Particular aspects of the proposed regulation, such as the previously mentioned Alternatives Analysis Threshold, may be more trade restrictive than necessary to fulfill the objective of the regulation, potentially in violation of Article 2.2 of the WTO TBT Agreement.

Second, as constructed, the proposed regulation will likely create less favorable conditions for suppliers outside of the U.S. during implementation. The Alternatives Assessment process, including the program to establish accredited bodies and subsequently, certified

¹ State of California Department of Finance “Economic and Fiscal Impact Statement (Regulations and Orders),” <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-399-7-17-2012.pdf>.

² California’s Health and Safety Code §25251 defines “consumer product” as, “a product or part of the product that is used, brought, or leased for use by a person for any purposes. ‘Consumer product’ does not include any of the following: 1) A dangerous drug or dangerous device...; 2) Dental restorative materials...; 3) A medical device...; 4) A food...; 5) Packaging associated with 1), 2), or 3); and, 6) A pesticide.”

assessors may also be inconsistent with Articles 2.1 and 7.1 (though its reference to Article 5.1) of the TBT Agreement. The accreditation and certification aspect of the alternatives assessment provisions appear to favor the specific capabilities of the U.S. university system. Alternatives assessment, generally speaking, may be accomplished using a number of different methodologies. There is not one correct way to complete such an assessment; and, not all cases of alternatives assessment require the same considerations or level of expertise in every discipline. In practice various industries and companies conduct alternatives assessments somewhat differently, according to the product segment and task at hand.

Protection of Confidential Business Information

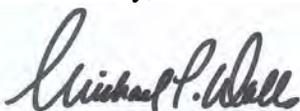
The proposed regulation requires an unprecedented level of information about products, chemicals, and manufacturers' business plans and operations to be made publicly available. ACC is particularly concerned that DTSC will not have the staff or physical resources to properly process, adjudicate, manage and store the volume of information that will be reported under the proposal. Much like U.S. federal and state laws protecting confidential business information and trade secrets, DTSC must also be mindful of Article 39.1 and 39.2 of the WTO TRIPS Agreement.

Article 39.1 and 39.2 of the WTO TRIPS Agreement require WTO members to protect undisclosed information, and to make it possible for natural and legal persons to prevent trade secrets from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices. The information that must be protected is information that is secret, in the sense that it is not generally known within circles that normally deal with that kind of information; that has commercial value because it is secret; and that has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

* * * * *

As drafted, the DTSC proposal establishes several unnecessary burdens to international trade that may violate the Technical Barriers to Trade Agreement. ACC believes that additional clarification of DTSC's intended scope and approach, and modification of the provisions noted above, will result in a regulatory system that more fully conforms to WTO practice and discipline while assuring a high level of health and environmental protection. If ACC may provide any additional information, please contact me.

Sincerely,



Michael P. Walls
Vice President
Regulatory & Technical Affairs



american cleaning institute*
for better living

October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
(via e-mail: gcregs@dtsc.ca.gov)

Re: Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the *Proposed Safer Consumer Products Regulations* released on July 27, 2012 by the California Department of Toxic Substances Control (DTSC or the Department) for the implementation of AB 1879 (2008).

ACI is the trade association representing the \$30 billion U.S. cleaning products market, with about \$3 billion associated with business in the State of California. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers. ACI and its members are dedicated to improving health and the quality of life through sustainable cleaning products and practices. ACI's mission is to support the sustainability of the cleaning product and oleochemical industries through research, education, outreach and science-based advocacy. As a trade association for a particular consumer product sector (cleaning products), we are acutely aware of the public's concern for the safety of the products they purchase both in their homes during use and in the environment following disposal. Human and environmental safety is at the core of the mission of our member companies and our association.

At the Federal level, ACI has been very active in engaging key legislators on the reform of the Toxic Substances Control Act (TSCA). Moreover, we have worked closely with the U.S. Environmental Protection Agency in their implementation of TSCA including a number of areas related to the proposed Safer Consumer Products regulations such as the prioritization of chemicals for risk assessment and the protection of trade secret information.

We have a number of detailed comments on the text of the proposed Safer Consumer Products regulations in an attachment to this letter, but would like to first share our perspective on some more general considerations in the proposed regulations.

Lack of Clarity Will Lead to Regulatory Uncertainty

The proposed regulations will be implemented through a series of vaguely described processes with many of the critical details being left for future guidance documents or regulatory findings. While such an approach is not unusual *to some extent* for regulatory development, the scope in this case is breathtaking, and will result in significant confusion in the marketplace. The proposed regulations do not comport with the Office of Administrative Law's standard of clarity – that is, “written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”¹ Because the regulations contain so many vagaries, the regulated community cannot know how they may comply. While DTSC has indicated that they will elucidate their intentions in the future, it does not appear that such findings and guidance will be consistent with the Administrative Procedure Act. DTSC has an obligation to provide clear and complete regulations for public review and comment such that the requirements on the regulated community are readily apparent. This is not just the law, but it is good public policy.

Distinguishing Between Intentionally-Added Ingredients and Contaminants

The proposed regulations do not make a distinction between intentionally-added ingredients and potential contaminants. Chemicals which are contaminants serve no useful function in a product. They should not be the subject of an alternatives assessment, and DTSC should not require one in such a situation – it is a poor use of resources for a company to conduct such an analysis and for the Department to potentially review it. We note that the proposed regulations *do* make such a distinction with respect to components of assembled consumer products defining them as “required to complete or finish an item,” “performs a distinctive and necessary function in the operation of a system,” or “is intended to be included as a part of a finished item.”² The same concepts should be extended to ingredients used in a formulated consumer product.

Additionally, we note that the regulations implementing the Children's Safe Products Act in Washington State define a *contaminant* as “trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.”³ The same regulations define an *intentionally added chemical* as “a chemical in a product that serves an intended function in the product component.”³ We believe this distinction is critical to the workability of the Safer Consumer Product regulations as the focus of the alternatives assessment will be the function of a chemical in a product. An alternatives assessment for a contaminant in a product is not a meaningful exercise. DTSC may well believe that manufacturers need to address and reduce contaminants in products. However, the present regulations, as designed, would not achieve such an objective.

As such, we request that DTSC include a definition of “contaminant” in the regulation that differentiates between intentionally-added ingredients and contaminants in products. Such a distinction and provisions for handling each appropriately are critical to the program's success.

¹ California Government Code, §11349(c)

² Section 69501.1(a)(21)

³ WAC 173-334-040 – What definitions apply to terms used in this chapter?
(<https://fortress.wa.gov/ecy/publications/publications/wac173334.pdf>)

Chemicals of Concern Identification Process

As currently written, the proposed regulations would establish Chemicals of Concern (COCs) based on 22 lists from various state, US Federal, and international government bodies. The Department has stated that this "List-of-Lists" comprises roughly 1,200 chemicals. We have conducted our own count of chemicals which are the subject of these lists and find they contain over 4,000 chemicals. The Department needs to articulate how it has determined that there are only 1,200 chemicals on these lists.

More importantly, as we have stated numerous times, the Department's approach continues to ignore the statutory mandate to identify and prioritize chemicals of concern. While it may be appropriate to use the various lists to identify candidate chemicals, there should be clear criteria and an established process for screening which chemicals are ultimately deemed a COC.

Consumer Product Prioritization Process

The Department included in this proposed regulation a number of prioritization factors and process steps to identify and list products as Priority Products. However, the factors and process are not transparent and it is entirely unclear how the Department would actually select a Priority Product. The Initial Statement of Reason (ISOR) states that the process identification includes a two-fold evaluation: 1) where a Chemical of Concern's behavior in terms of its toxicity and physical profile in the product, and 2) exposures to the Chemical of Concern in the product in quantities that may contribute to or cause enumerated adverse impacts. This is an appropriate framework to use. However, the execution of that evaluation would be entirely internal within DTSC. The details provided in the regulation and associated documents are insufficient permit prediction of an end result, and leave too much discretion to the Department. The proposed process lacks sufficient transparency such that decisions by the Department on Priority Products will not be greeted with confidence by stakeholders.

In determining the Initial Priority Product List (Section 69503.3(g)) for the first three years of the program (roughly), the Department would focus only on those chemicals that are found on one of the 14 lists under Section 69502.2(a)(1) and on one of the 8 lists under Section 69502.2(a)(2). We note that the former 14 lists are viewed by DTSC as hazard trait lists and the latter 8 lists are viewed as exposure/monitoring related lists. We believe that the approach for selection of Chemicals of Concern and Priority Products should consider both hazard traits and exposure. The approach proposed by the Department is pragmatic, though potentially subject to criticism. Nonetheless, we believe it is suitable for the initial list of Priority Products. However, going forward beyond the initial stages of the program, the Department should have an approach that considers elements of hazard and exposure more rigorously.

In selecting Priority Products, the Department should use a standardized product nomenclature system. We note that the ISOR makes reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing Section 69503.3(f). We agree that the GS1 GPC is an appropriate source for describing products and that Priority Products should be identified at the Brick Level. Priority Product categories should be described at the Class Level for the purposes of the Department's Priority Product Work Plan.

Alternatives Analysis Threshold Determination

ACI is greatly troubled by the Department's abandonment of the simple concentration based approach it had proposed earlier in favor of a process-based approach that will be primarily based on the minimum detectable concentration for the Chemical of Concern in a product. Moreover, we find it disturbing that the Department proposes this approach even though it acknowledges that the AA Threshold may well be below a level that represents an insignificant or negligible risk, too small to be of concern. It is unclear why the Department would impose such heavy regulatory burdens on companies in cases where it knows there is little or no opportunity to improve public protection or improve environmental quality.

In the interest of regulatory efficiency, we recommend that the Department return to its previous proposal (October 31, 2011) of an administrative, concentration-based AA Thresholds of 0.01% for chemicals with particular hazard traits (e.g., carcinogens, neurotoxins, reproductive toxicants, etc.) and 0.1% for all other chemicals until it can develop a credible risk-based approach.

We believe that any process-based approach should be self-implementing and risk-based. An example is the Proposition 65 Safe Harbor provisions which are used by companies to determine whether they have to label a product as containing a Prop 65 chemical. We believe that no Prop 65 chemical should have an AA Threshold below its No Significant Risk Levels for carcinogens or the Maximum Allowable Dose Level for chemicals causing reproductive toxicity.

Regulatory Duplication

The California Health and Safety Code § 25257.1 prohibits the Department from superseding the regulatory authority of any other California department or agency and from duplicating or adopting conflicting regulations for product categories already regulated. There are a number of conflicts in the proposed regulations with other California agencies and various laws. For example, the California Division of Occupational Safety and Health is responsible for regulating worker exposures in occupational settings and the California Air Resources Board has extensive regulatory oversight of volatile organic compounds (VOCs) in consumer products. At the Federal level, over-the-counter drugs and food contact materials are regulated by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act. The Department should clearly articulate the limits of the regulations so that it complies with Section 25257.1.

Peer-Review of Scientific Components

The notice for the proposed rule states that DTSC is having the scientific basis of these regulations peer reviewed pursuant to Health and Safety Code § 57004. We believe that the Department should select peer-reviewers who are familiar with the context of the regulations and have some experiences with the many challenges DTSC is facing in developing the regulations. We recommend that DTSC publicly release the charge questions for peer-reviewers and solicit comments on the charge questions in advance of the initiation of the peer-review.

CEQA Exemption

The notice for the proposed regulations stated that DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.) and DTSC prepared a Notice of Exemption from the California Environmental Quality Act. While it might be difficult to quantify all of the potential impacts of the proposed Safer

Consumer Products regulations at this time, that does not justify a complete exemption from such an analysis. DTSC should initiate CEQA analysis as part of this rulemaking.

We believe several impacts of the regulations can be anticipated and analyzed. For example, because the Alternatives Assessment Threshold would be primarily based on the minimum detectable concentration for the COC in a product we believe that will drive manufacturers to seek high purity source materials for their products. This will result in several impacts:

- 1) Recycled materials would be disfavored in the market because of residuals present in them, or merely because their purity cannot be guaranteed easily. As a result, the price for such materials will decline leading to reduced viability of recycling collection and distribution systems. This may directly impact California municipalities and may require greater disposal of diverted recyclable material.
- 2) Similarly, complex natural materials would be disfavored for the same reasons that recycled materials would be. Complex substances that could be derived directly from a natural source will lose favor in the market to complex substances synthesized from known feedstocks; the feedstock could be synthetic (petrochemical) or natural in its source. However, bio-based materials could be disadvantaged by the construct of the final rule.
- 3) Manufacturers will seek higher purity source material that will require greater processing to remove residuals. This would require greater energy for purification and higher costs of feedstocks. Life-cycle inherent energy in products will increase.

There are likely other macroeconomic impacts that could be anticipated based on policies incorporated into the regulations that are currently not assessed. To the extent that it is possible to do so, such an analysis should be initiated.

ACI would like to express, once again, its appreciation in being able to comment on the proposed Safer Consumer Product regulations. We would be happy to further assist DTSC in the development of regulations implementing AB 1879 by sharing our expertise and the expertise of our members. If you have any question regarding our submission, please feel free to contact me by phone at 202-662-2516 or by e-mail at pdeleo@cleaninginstitute.org.

Sincerely,



Paul C. DeLeo, Ph.D.
Senior Director, Environmental Safety

Enclosure

cc: The Honorable Matthew Rodriguez, Acting Secretary, CalEPA (MRodriguez@calepa.ca.gov)
Debbie Raphael, Director, DTSC (DRaphael@dtsc.ca.gov)
Odette Madriago, Acting Chief Deputy Director, DTSC (OMadriag@dtsc.ca.gov)
Colleen Heck, Senior Staff Counsel, DTSC (CHeck@dtsc.ca.gov)

SPECIFIC COMMENTS – DRAFT

Article 1. General

Section 69501.1 – Definitions

- (3) Adverse air quality impacts – revise to read “means air emissions of any of the air contaminants listed below in quantities that present an unacceptable public health or environmental risk.”
- (4) Adverse ecological impacts – this definition lacks clarity regarding the threshold at which the stated adverse impacts occur. The definition should be revised so that those thresholds are clearly identified.
- (6) Adverse public health impacts – We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.^{4,5} We maintain that the regulations, as proposed, include many elements that are not authorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. As such, the Safer Consumer Product regulations should not reference Chapter 54.
- (8) Adverse soil quality impacts – revise to read “means emissions to soil of contaminants in quantities that present an unacceptable public health or environmental risk.”
- (9) Adverse waste and end-of-life impacts – the definition is unclear. No adverse impacts are identified. The definition should be revised to indicate what adverse waste and end-of-life impacts are covered by the definition.
- (10) “Adverse water quality impacts” – it should be clear that any of the “increases” cited in the definition should be of a magnitude that result in an unacceptably high increase in risk to public health or the environment. With respect to subsections (A) “Increase in biological oxygen demand” and (B) “Increase in chemical oxygen demand,” they are effectively measures of biodegradability and the oxidizable (carbon) content of a chemical; these are generally not characterized as adverse impacts. Likewise, in subsection (D), “total dissolved solids” is simply a description of physical state of a material within water. These three subsections should be eliminated or a threshold at which the increase is adverse should be defined.
- (17) Bioaccumulation – Recently, the Society of Environmental Toxicology and Chemistry (SETAC) conducted a Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of

⁴ <http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf>

⁵ <http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf>

bioaccumulation science.^{6,7} Much of this science was discussed at the May 2010 OEHHA workshop in Berkeley, California on *Indicators of Ecotoxicity Hazards and Exposure Potential*. The SETAC workshop developed the following definition for a bioaccumulative substance: “A substance is considered bioaccumulative if it biomagnifies in food chains.” Standard criteria for reporting the extent to which a chemical may bioaccumulate were noted including trophic magnification factor (TMF), biomagnification factor (BMF, both laboratory and field), bioaccumulation factor (BAF), bioconcentration factor (BCF), octanol-water partition coefficient (K_{OW}) and octanol-air partition coefficient (K_{OA}). The workgroup concluded that the most relevant bioaccumulation criterion is the trophic magnification factor (TMF; also referred to as a “food-web magnification factor”); in the absence of data on the TMF, the BMF (either derived in the laboratory or based on field data) is a reliable indicator. They also concluded that “[t]he BCF is no longer recognized to be a good descriptor of the biomagnification capacity of chemical substances” and “that the K_{OW} is a highly useful chemical specific descriptor of the bioaccumulation potential of chemicals in fish and many other water breathing aquatic organisms.” The SCP regulations should use a similar definition of bioaccumulation and accommodate these five criteria (TMF, BMF, BAF, K_{OW} , and K_{OA}) as appropriate means of measuring bioaccumulation potential. In addition, the regulations should establish thresholds for what constitutes a bioaccumulative chemical using each of the criteria consistent with the scientific consensus of the Pellston workshop (TMF > 1, BMF > 1, BAF > 5,000, Log K_{OW} > 4, Log K_{OA} > 5) and in a tiered order of preference (TMF > BMF > BAF > K_{OW} or K_{OA}).

- (19)(A)2. Chemical ingredient – revise to read “means a chemical intentionally used in a consumer product to impart a particular function in the product.” This definition should be made consistent with other state or Federal statutes or regulations whereby ingredients are recognized as functional components of a product intentionally added to impart a function. For example, the FDA’s cosmetics regulations provide the following definition for an ingredient: “The term ingredient means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product” [21 CFR 700.3(e)].
- (20) Chemical of concern – The definition should be based on the Departmental listing, not on lists developed by other authoritative and non-authoritative bodies. Revise to read “means a chemical ingredient identified as a Chemical of Concern under section 69502.2(a), or a chemical listed by the Department under section 69502.3(b).” In the spirit of the statute (AB 1879), Chemicals of Concern should be limited to those ingredients intentionally added to a consumer product by a manufacturer in order to impart a function in the product. Moreover, by focusing the scope of the regulations, the stated intent of the Department to encourage

⁶ Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.

⁷ <http://www.setac.org/sites/default/files/ExecutiveSummary.pdf>

manufacturers to consider the necessity of ingredients in their products will be better effectuated.

- (29) Environmental or toxicological endpoints – We have commented twice before on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), and those comments are currently available on the OEHHA website.^{8,9} We have noted the serious flaws in the process used by OEHHA; its unwillingness to consider comments from their peer-reviewers and the public at large, including numerous subject matter experts; and the flawed science at the heart of the regulation. We urge DTSC to reject this definition and the entire OEHHA regulation, and to develop scientifically sound definitions of environmental and toxicological endpoints.
- (32) Hazard trait – Hazards are, in the context of chemicals, inherent properties that have the potential to lead to adverse effects in humans or wildlife under particular conditions and levels of exposure. In the context of the present regulation, they are toxicities. The definition should be amended accordingly and reference to chapter 54 eliminated.
- (43) Persistence – Reference to section 69405.3 should be eliminated and the definition should read as follows: “means the propensity for an organic chemical substance to exist in an environmental medium (e.g., water, soil, sediment, air) in an unchanged form. The thresholds for a substance to be designated as a persistent substance are as follows: a half-life of greater than 60 days in water (marine or freshwater), greater than 180 days in soil or sediment, or greater than 2 days in air.”
- (52) Reliable information – the proposed definition lacks any description or characteristics of what constitutes reliable information or studies. Publication of a report or study, whether in a peer-reviewed journal or otherwise, is no guarantee that the underlying data and information are appropriate for regulatory decisions. While the information sources cited in the definition may be appropriate to consider in a weight-of-evidence decision-making scheme, an entirely separate process is necessary to ensure that the information used is in fact a well conducted study. We support definitions of “reliable information” and “a well conducted study” consistent with the approach used by the Organization of Economic Cooperation and Development (OECD) in their Manual for Investigation of HPV Chemicals. As such, we suggest: *“Reliable information” is from studies or data generated according to valid and accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship (“QSAR”) approaches may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD)*

⁸ <http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf>

⁹ <http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf>

in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, December 2009) shall be used for the determination of reliable studies.

The definition of “authoritative organization” should include the Organization for Economic Cooperation and Development, and its member countries.

- (53) Reliable information demonstrating the occurrence of exposures to a chemical – Subsection (C), which includes chemical properties and does not inform whether exposure has occurred and should be eliminated. For subsection (D), modeling results may be important for exposure assessments but exposures estimated from models should be confirmed with collected monitoring data; as such, subsection (D) should be eliminated.
- (54) Responsible entity – The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the Federal Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (CARB, CPSC, etc.). All consumer commodities that are legally distributed in U.S. commerce must comply with the Federal Trade Commission labeling requirements, so identification of the responsible entity is simple. As such, subsections (B) and (C) should be eliminated.
- (56) Safer alternative – revise to read “means a functionally acceptable alternative that, ...”

Section 69501.2 – Duty to Comply and Consequences of Non-Compliance

- In Section 69501.2(a), the requirements for compliance should be limited to the manufacturer of the product. As such, references to the importer or retailer should be eliminated.

Section 69501.3 – Information Submission and Retention Requirements

- The certification statement would create a new crime, and DTSC does not have that authority. It is sufficient that an officer of the company responsible for the information submission sign the documents.

Section 69501.4 – Chemical and Product Information

- Under subsection (a)(4), the Department would give itself unlimited authority to require a manufacturer or importer to generate and obtain information with no accountability. There should be boundaries regarding the kind of information that the Department may seek, and due process for those for whom the Department is making the request.

Section 69501.5 – Availability of Information on the Department’s Website

- The Department should use official state regulatory dissemination methods (e.g., California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the Safer Consumer Product regulations.

- The Department proposes to require itself to post non-critical information on its websites. These provisions should be eliminated from the regulations as requirements, but the Department might optionally post them electronically as resources are available for such lower priority tasks. As such, the following subsections under Section 69501.5(a) should be eliminated: (4), (5) and (8). The following subsections under Section 69501.5(b) should be eliminated: (4), (5), (6), and (8).

Article 2. Chemicals of Concern Identification Process

The mechanisms for identifying Chemicals of Concern, namely, an initial listing, a Departmental listing process, and a petition process are good components to this section.

Section 69502.2 – Chemicals of Concern Identification

- Section 69502.2(a): Initial Chemicals of Concern List – The process contemplated for initial listing of chemicals has some good core elements, namely the identification of severe hazard traits and the use of existing authoritative listings to rapidly identify chemicals which have those severe hazard traits. However, we recommend additional criteria and screening parameters which will make the listing process more credible and transparent.
 - We recommend that the initial listing focus on known carcinogens and reproductive and developmental toxicants. In addition, the list should focus on persistent, bioaccumulative and toxic (PBT) substances using criteria consistent with the US EPA's definition of PBT substances.
 - A number of the proposed lists are not good sources and should not be used:
 - The Category 1 endocrine disruptors list (1)(C) has been disavowed by EU authorities. Endocrine disruptors will be captured by those chemicals identified as developmental or reproductive toxicants.
 - The Washington State PBT list (1)(N) did not use criteria consistent with the US EPA PBT list (1)(K).
 - The OSPAR list (2)(H) is not an authoritative list.
 - Using the other lists identified in the proposed regulation as potential sources to identify Chemicals of Concern, the Department should further screen the chemicals included to only those permitted in commerce in the United States, those chemicals that are in commerce in California large volumes, and those chemicals that are known to be used in consumer products. By using such screens, the Department will be left with a manageable and meaningful list of Chemicals of Concern.
- Section 69502.2(b): Additions to the Chemicals of Concern List – the narrative standard for identifying additions to the Chemicals of Concern list is not sufficiently transparent. The Department needs to provide additional clarity to this process so that it is objective and

repeatable if conducted by different sources. There is no indication what sorts of thresholds for the factors would be used in selecting additional Chemicals of Concern.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

Section 69503.2 – Priority Product Prioritization Factors

- While the principles embodied in this section are appropriate, the application of them is unclear. The decisions by the Department are likely to appear to be arbitrary if they are not *in fact* arbitrary. The Department should clarify how the prioritization of priority products will occur so that decisions are transparent before they are made.

Section 69503.5 – Alternative Analysis Threshold Exemption

- The Alternative Analysis Threshold Exemption process should be eliminated in favor of a self-assessment process. OEHHA uses a self-assessment process under the Proposition 65 Safe Harbor provisions for companies to determine whether they have to label a product. This aspect of Prop 65 has been very successful and may be a model for the application of the *de minimis* provisions of the Safer Consumer Product regulations.

Article 5. Alternatives Assessments (AA)

Section 69505 – Guidance Materials

- Under subsection (a), it is critical that substantive guidance documents be prepared and disseminated prior to Priority Products subject to the Alternatives Assessment process being identified. This provision should be retained.

Section 69505.1 – Alternatives Assessments: General Provisions

- Subsection (h) would require the responsible entity to consider all relevant information made available on the Department's website. The Department's website is quite extensive and the Department intends to add numerous new elements under this program. This would be an enormous quantity of information for any entity to review. Since the Department will be best suited to know what materials on its website are appropriate for a particular Alternatives Assessment, they should specify them. Subsection (h) should be eliminated and the Department should instruct the AA preparer as to what information it believes is important for the preparer to consider in its assessment. Such guidance also will have the advantage of fostering consistency among assessments from multiple manufacturers for the same Chemical of Concern in a particular consumer product.

Section 69505.4 – Alternatives Assessment: Second Stage

- For Section 69505.4(a)(2)(A), the multimedia life cycle impacts and chemical hazards assessment should be limited to the chemical(s) of concern in the priority product that are the subject of the alternatives assessment, and not all ingredients in the product. Replace "chemical ingredients" with "Chemicals of Concern."

- Section 69505.4(a)(2)(C) – Economic Impacts should be eliminated as this will be well beyond the expertise of most responsible entities and any consultants they may hire to help prepare the AA report. Further the information is not relevant to the selection of an alternative and represents an undue burden to the responsible entity. The information may be relevant to the Department with respect to a regulatory response however the Department should find a more appropriate means of generating this data.
- Section 69505.4(c) – Step 3, Alternative Selection Decision should be eliminated. It is inappropriate and impractical for responsible entities to be incorporating their business plans in an AA report.

Section 69505.5 – Alternatives Assessment Reports

- In Section 69505.5(a)(4), the Department would require the responsible entity to include sufficient information in the Final AA Report for the Department to determine the appropriate regulatory response. The responsible entity cannot know what information is sufficient for the Department to make a decision. This requirement is unnecessary and inconsistent with the statute and should be eliminated from the regulations.
- Section 69505.5(d)(3) would require the name and contact information of all persons to whom the manufacturer or importer directly sold the Priority Product in California to be submitted to the agency. There are a number of large direct selling companies who do business in California and who have tens of thousands of independent business operators to whom they sell their products for further sale to consumers. For the state to require the name and contact information of potentially tens of thousands of private citizens to be submitted to the agency is both impractical and unnecessary. This provision should be removed from the regulations.
- Section 69505.5(e) should be revised to read “A description and location of the facilities in California where the Priority Product is produced.” The state cannot extend its authority beyond its borders.
- Section 69505.5(i)(2) appears to be an attempt to identify data gaps that might exist. The Department should clarify that this is the intent of this provision.
- Section 69505.5(j) would require the Final AA Report to identify and describe the alternative that is selected. This requirement is unnecessary for the effectuation of the regulations including the Regulatory Response from the Department. These kinds of business decisions are very sensitive and may be very fluid for a company. Moreover, the Department lacks the authority to “approve” whether a particular product is permitted to be on the market. The Department’s authority is specific to requiring an alternatives analysis to be conducted and for the Department to make a Regulatory Response with respect to that analysis. The Department does not have the authority to pick winners and losers in the market place and to

dictate what products a company may or may not produce. This section and its associated subsections should be stricken from the regulation.

- Section 69505.5(j)(2)(C) would require a list of all chemical ingredients known to be in the selected alternative that differ from the ingredients in the Priority Product or that are present at a higher concentration in the selected alternative to be submitted to the agency, as well as all available chemical identification and hazard information for those chemicals. This information is completely irrelevant to the alternatives assessment or the regulatory response. It is completely unnecessary. This section should be eliminated from the regulations.

Article 6. Regulatory Responses

Section 69506 – Regulatory Response Selection Principles

- This section conflicts with the statutory provision in section 25253. There, the Legislature has established the standard for evaluating chemicals of concern in consumer products and their potential alternatives “to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.” Limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection. This section should be revised to more clearly reflect the intent of the statute.

Section 69506.2 – AA Report Supplementary Information Requirements

- This section would give the Department unlimited authority to obtain information from the responsible entity. The statute does not give the Department such unlimited authority. This section should be clarified to specify the boundaries of the Department’s authority.

Section 69506.3 – No Regulatory Response Required

- This section provides that no regulatory response is required if the Department determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts. Perhaps the Department believes that referring to preventing or limiting public health and environmental impacts is an adequate standard, but the truth of the matter is that it is little more than a tautology. That is, no regulatory response is required if the Department determines that no regulatory response is required. The Department should articulate the standards by which a determination is made that no regulatory response is required.

Section 69506.5 – Product Information for Consumers

- The Consumer Product Safety Commission (CPSC) has regulations specific to the labeling of product information on packages. CPSC requires identification on the label of those chemicals that are responsible for a hazard warning appearing on a label. They see this as critical to the consumer having access to essential, focused information that they can provide

over the phone to medical personnel in the case of an accidental exposure. Likewise, Poison Control Centers share a similar concern regarding product labeling. The Department should reconsider whether it is wise (and consistent with Federal regulations) to require product labeling (Section 69506.3(b)(2)(A)) that distracts from important safety warnings. Furthermore, the regulations should permit the dissemination of this information through electronic (website) or telephonic means.

Section 69506.5 – Use Restrictions on Chemical(s) of Concern and Consumer Products

- This section imposes restrictions on the use of one or more chemicals of concern and a selected alternative or in a priority product for which no alternative is selected or on the use of the product itself. The section spells out what the use restrictions may be, but it contains no standards as to when these restrictions may be imposed. The section simply says, “The Department may impose restrictions.” Again, the Department has conferred unfettered and arbitrary discretion on itself. The standards by which such restrictions would be made by the Department should be clearly articulated.

Section 69506.6 – Product Sales Prohibition

- Subsection (a) of this section provides that the section does not apply to a product that does not contain any chemical of concern above the applicable alternatives analysis threshold. Subsection (b) provides “except as provided in section 69506.3” a sale prohibition may be imposed if a selected alternative contains one or more chemicals of concern or if no alternative is selected for a priority product and “there is a safer alternative that does not contain a chemical of concern and that is both functionally acceptable and technically and economically feasible.”

Perhaps a sales prohibition is appropriate in the circumstances set out in subsection (b). However, note that subsection (d) provides that the Department may issue a notification prohibiting the sale of a product “notwithstanding that there are no current identified safer alternatives that are both functionally acceptable and technically and economically feasible.” Subsection (d) contains no standards as to when the Department would issue a notification prohibiting the sale.

It should be noted that subsection (d) supersedes subsection (b) by allowing the Department to prohibit the sale whenever it chooses. Again, the absence of any standard enables the Department to impose unfettered and potentially arbitrary discretion.

Section 69506.7 – Engineered Safety Measures or Administrative Controls

- This section allows the Department to impose requirements that control access to or limit exposure to chemicals of concerns, to reduce the likelihood of adverse public health and/or environmental impacts. Subsection (b) sets out three circumstances when engineering or administrative controls may be imposed by the Department. However, they are themselves

inadequate. Engineering or administrative controls should be implemented to reduce real human health or environmental risks. This section should be revised to more fully consider the level of analysis necessary to make such determinations.

Section 69506.9 – Advancement of Green Chemistry and Green Engineering

- This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals. No standards are set out as to when the Department would do that. Again, the Department has conferred on itself unfettered and potentially arbitrary discretion. Appropriate standards indicating when such a research program would be required should be articulated in the regulation.

Section 69506.10 – Regulatory Response Selection and Reevaluation

- Subdivision (a) of this section provides that the Department may impose one or more regulatory responses specified in the preceding sections to situations other than those specified in those sections. As noted before, many of those sections do not contain specified situations. But here, the Department has conferred complete discretion on itself to impose any regulatory response under any set of circumstances that it may choose.

Section 69506.11 – Exemption from Regulatory Response Requirements

- This section is ostensibly designed to implement the provision in section 25257.1 of the statute. Subdivision (b) of the statutory section provides that, “This article does not authorize the Department to supersede the regulatory authority of any other department or agency.” Subdivision (c) provides that, “The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.”

Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response “substantially duplicates” one or more requirements of another California or federal regulatory program, “without conferring additional public health or environmental protection benefits.”

Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department, providing the article does not authorize the Department to supersede, duplicate, or adopt conflicting regulations. The Legislature has imposed responsibility on the Department to implement that provision. It does not contemplate imposing the burden on responsible entities.

The Department exceeds its authority in subsection (a)(6)(B). The statute does not authorize the Department to duplicate other regulatory programs if the Department is conferring greater public health or environmental protection.

Finally, the Department has ignored the fact that section 25257.1(b) of the statute prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, supersedes the other agency's regulatory program. The Department is specifically prohibited by section 25257.1 from doing that. As such, the Department should acknowledge in the regulations that it is prohibited from superseding the regulatory authority of any other department or agency.

Section 69506.12 – Regulatory Response Report and Notifications

- This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. Section 25253(b) of the statute provides that the regulations adopted pursuant to this section shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. The notification to the retailers is not designated as a regulatory response. Rather, it is applied to a responsible entity after a regulatory response is imposed on that entity. Nothing in the statute authorizes the Department to impose such a reporting requirement. It exceeds the scope of the authority to specify the range of regulatory responses and should therefore be removed.

Article 7. Dispute Resolution Process

Section 69507.1 – Informal Dispute Resolution Procedures

- It should be the option of the party bringing forward the dispute whether they choose to follow the formal or informal dispute resolution process, and all Departmental decisions should be permitted to follow the formal dispute resolution process. However, the processes should be sequential with the option of an informal review occurring before a formal review.
- Failure to select a particular dispute resolution option should not preclude other administrative or non-administrative review of a Departmental decision (e.g., judicial review) that may be available.

Article 8. Accreditation Bodies and Certified Assessors

- The entirety of Article 8 is unnecessary to the efficient implementation of the statute and should be eliminated. The Department will be working closely with responsible entities preparing Alternatives Assessments, and given the authority of the Department to restrict or prohibit the use of a chemical of concern in a consumer product, the responsible entities will be highly motivated to comply with the regulations.

Article 9. Audits

- This article while describing the scope of coverage lacks clarity in its purpose and consequences. Of particular note is subparagraph (b)(3) – Implementation of the selected alternative. This implies that the Department will be auditing the business decisions of a company and making sure that they make the “right” choice. There is no evidence to suggest that DTSC is qualified in the least to design, manufacture or market products, or that it should be selecting which products are appropriate to be on the market. The Department should amend the regulations to clearly indicate the standards against which the audited documents are being compared. Further, subparagraph (b)(3) should be eliminated as it is unnecessary for the effectuation of the statute and unauthorized.

Article 10. Trade Secret Protection

Section 69510 – Assertion of a Claim of Trade Secret Protection

- Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes.

Subsection (a) requires somebody making a claim for trade secret protection to provide specific information. Here, they are set out as subsection (6), the estimated value of the information to the person and the person’s competitors; (7) the estimated amount of effort and/or money expended by the person in developing the information; and (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering.

In addition, subsection (10) requires a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed.

Further, subsection (11) requires the signature of the general counsel or other executive, certifying under penalty of perjury that there is a basis for asserting a trade secret protection.

Subsections (a)(6), (a)(7), (a)(8), (a)(10) and (a)(11) should be eliminated

- Subsection (f) states that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trade submission or any chemical identity information associated with a hazard trade submission. This exceeds the scope of the statutory authority precluding protection for hazard trade submission but not chemical identity and is in conflict with the California Uniform Trade Secret Act and the Uniform Trade Secrets Act. It should be eliminated.
- Subdivision (g) provides that trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the claim is for a

proposed alternative to a chemical of concern in a priority product subject to certain requirements. Those requirements include demonstrating to the Department's satisfaction the chemical is a new chemical or a new use of an existing chemical, provide the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing chemical of concern of the priority product, and comply with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret in conflict with the California Uniform Trade Secret Act and the Uniform Trade Secrets Act. It should be eliminated.



AmericanCoatings
ASSOCIATION

October 9, 2012

Ms. Krysia Von Burg, Regulations Coordinator
Regulations Section
California Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Via Electronic Mail Only to gcregs@dtsc.ca.gov

RE: ACA Comments on the July 27, 2012 DRAFT California Safer Consumer Products Regulations

Dear Ms. Von Burg:

The American Coatings Association (ACA) is submitting these comments on the latest draft of the California Safer Consumer Product Alternatives Regulations. ACA is a voluntary, nonprofit trade association representing some 350 manufacturers of paints, coatings, adhesives, sealants, and caulks, raw materials suppliers to the industry, and product distributors. Our membership represents over 90% of the total domestic production of paints and coatings in the United States. Our membership includes paint and coatings manufacturers, raw materials suppliers, distributors, as well as approximately 2,000 coatings formulators and scientists.

The manufacture, sale, and distribution of paints and coatings are a \$20 billion dollar industry in the United States. Our industry operates in all 50 states, and employs over 60,000 people engaged in manufacturing and distribution. The state of California currently represents approximately 18% of our domestic coatings sales market.

ACA appreciates the opportunity to submit these comments to DTSC. As this is the eighth draft of these regulations, our comments are more concise.

Respectfully Submitted,

Stephen R. Sides, CIH
VP, Science, Technology, and Environmental Policy

Alison A. Keane, Esq.
VP, Government Affairs

Duty to Comply and Consequences of Non-Compliance (Section 69501.3)

In our previous comments, ACA asked that the regulations make clear whether or not DTSC would allow a collective approach to the development of an Alternatives Analysis, specifically allowing an AA to be submitted by a trade association or consortium as an alternative to an AA submitted by an individual company. ACA also suggested anti-trust language be added to undertake a collective AA.

Although regulations now clearly state that manufacturers wishing to work with a consortium to conduct an AA will have the option of doing so on their own to protect trade secrets, the regulations don't contain any anti-trust language either.

Suggested Anti-Trust Language to Allow Collective Action for AAs

This language would be necessary for multiple product manufacturers or a third party representing the product manufacturers to collectively undertake the alternative assessment for a consumer product and/or fund such activity, particularly if the funding mechanism was based on market share. In addition, if there is an aggregated externalized cost identified, it would protect the identification of such collectively by competitors.

Note: This suggested anti-trust language may need to be inserted into a brand new section. It should be examined by DTSC Counsel for form and sufficiency.

“(a) Except as provided in subdivision (c), action taken solely to comply with this chapter, including alternative assessments and identifying potential alternatives for Priority Products, undertaken by multiple responsible entities or a third-party organization funded by participating responsible entities is not a violation of the statutes specified in subdivision (b).

(b) The following statutes are not violated by an action specified in subdivision (a): (1) The Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions

Code). (2) The Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code).

(c) Subdivision (a) shall not apply to any agreement establishing or affecting the price of consumer products, except for aggregate externalized costs, or the output or production of consumer products, or any agreement restricting the geographic area or customers to which consumer products will be sold.”

Acknowledging Reformulation Efforts in Advance (Section 69501.4)

In our last set of comments, ACA suggested that DTSC designate an area on its website to acknowledge manufacturers who reformulate their products in advance of being required to do so by DTSC. In this latest draft of the regulations, DTSC has now created a “Safer Consumer Products Recognition List” that will highlight those manufacturers who have voluntarily provided information, completed and Alternatives Assessment on a product not listed for regulation, or provided helpful information to DTSC. The “Safer Consumer Products Recognition List” is a nice idea, but it doesn't go far enough. The intent

behind our suggestion was to have the web notice provide a simple way (involving no required reporting) for voluntary action instead of the “Priority Product Removal Notice” under Section 69501.2 that DTSC will require from manufacturers. DTSC is retaining control and not allowing voluntary action, which only creates more work for the agency.

Chemicals of Concern Identification (Section 69502.2)

We are pleased to hear that the number of Chemicals of Concern (COC) on the Initial Chemicals of Concern List has been reduced from over 3000 to about 1200. However, we still believe that 1200 chemicals is way too large a number to be used as a starting point for regulatory purposes. We still advocate a list of 300 or less chemicals of concern that are prioritized according to the newly established EPA prioritization principles, or some other science-based prioritization scheme.

Priority Products Prioritization Factors (Section 69503.2)

The inclusion of prioritization factors is a welcome change to these regulations. In particular, ACA notes that DTSC will consider whether the product is captured under some other regulatory program and also whether there is significant ability for the public, animals, or plants to actually be exposed to the COC in the product in quantities that would adverse health or environmental effects.

Priority Products List (Section 69503.4)

ACA notes that DTSC has finally committed *in writing* to an initial list of not more than five (5) priority products. It is very helpful to have this in writing, as it seems to indicate that DTSC will take a cautious approach to implementing the program. This is a wise approach. However, we still remain concerned that one chemical of concern in one product of concern could impact thousands of coatings formulations.

Alternatives Analysis Threshold Exemption (Section 69503.5)

ACA would prefer that DTSC define this section as “de minimis”, rather than “alternatives analysis threshold”, as the term “de minimis” more clearly acknowledges that the risk is not actionable. However, we do believe that evaluating thresholds on a chemical by chemical basis does provide more flexibility for industry and DTSC.

Priority Product Notifications (Section 69503.7)

In previous drafts DTSC had set a deadline of 60 days for Priority Product Notification. ACA asked that for formulated products, like paint, the deadline be extended to at least 180 days. We believe that DTSC should strongly consider extending the 60 day timeline to 180 days for formulated products, due to a more complex supply chain.

Alternatives Analysis: General Provisions (Section 69505.1)

In our previous comments, ACA requested that for formulated products, like paint, the deadline for preliminary Alternative Analysis Report be extended to 12 months for the preliminary AA Report and 18 months for the final report due to the complex supply chain for formulated products. We still believe these extensions are absolutely necessary for full compliance.

Product Information for Consumers (Section 69506.4)

The large "Chemicals of Concern List" means that most products regulated under this section will require extensive labeling. It is unclear whether DTSC has considered how that requirement will interfere with existing labeling regulations that already strain limited label space, especially for smaller-sized products. DTSC's suggested alternatives (an accessible manual or point-of-sale posting) are inflexible given the sheer variety of products that may be subject to alternatives assessments over the years.

If an alternative is not selected, DTSC should require identification only of the COC that caused the priority product listing in the first place. If an alternative is selected, but not yet formulated into the product, and that product contains other listed COCs, then only that COC that serves the same function as the pending alternative COC should be required to be identified. Otherwise, the manufacturer will be placed at an unfair disadvantage relative to competitive products that did not happen to contain the COC that caused the priority product listing, but may contain other COCs.

End-of-Life Management Requirements (Section 69506.8)

The current regulations authorize DTSC to require a regulatory response requirement for a product that is an alternative, and for priority products for which an alternative is not selected, or that will remain in commerce in CA pending development and distribution of a selected alternative, to protect public health and the environment and maximize the use of alternatives of least concern. Of major concern to ACA is a very detailed and onerous end-of-life management program that is one of many regulatory response requirements that DTSC can impose. A significant requirement of the end-of-life program is that compensation must be provided to retailers who agree to administer or participate in the collection program. ACA previously requested that PaintCare and any other end-of-life management program be exempt from a regulatory response if the responsible entity is participating in an end-of-life management or extended producer responsibility program that is currently required pursuant to a different California statute or regulation.

While the regulations offer an opportunity to apply for a regulatory response exemption, its approval is left up to DTSC's discretion and allows DTSC to go beyond what is already in the CalRecycle PaintCare regulations pursuant to AB 1343. It places the burden on the manufacturer to apply to the department for an exemption from a regulatory response that conflicts with one or more statutory requirements, or substantially duplicates one or more statutory requirements -- "without conferring additional public health or environmental protection benefits." Such vague wording would grant DTSC the authority to require specific EPR components that were intentionally left out of AB 1343 by ACA, allowing a back door way for CalRecycle and DTSC to push PaintCare towards a government run, command and control EPR program that the agencies could not get passed in the Legislature. Also, even though subsection (c)

of the end-of-life management requirements authorizes the manufacturer to substitute an alternative end-of-life management program, such substitution must achieve "to the maximum extent feasible, the same results as the program required by this section." Such substitution also can't be instituted by the manufacturer unless the manufacturer receives advanced written approval from the Department ***even though the statute already requires implementation of PaintCare – a very real Catch 22***. Ultimately, the "maximum extent feasible" and "written approval" requirements could saddle PaintCare with both an end-of-life management program administered by DTSC as well as by CalRecycle. Such uncertainty, just as PaintCare is being established by the coatings industry pursuant to statute in this state, is unwarranted and unworkable.

Further, the Green Chemistry statute in S. 25257.1 (b) and (c) provides that DTSC is not authorized "to supersede the regulatory authority of any other department or agency" or "duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." ACA will continue to request that the regulations be amended to be consistent with the specific language of the Green Chemistry statute. Manufacturers should be clearly exempt from the end-of-life management regulatory response if the manufacturer is participating in an end-of-life management or product responsibility program mandated by statute in this state, and should not have the burden to request an exemption in such cases. In addition, the regulations should delete the ability of DTSC to impose an end-of-life management program even if it provides additional public health or environmental protections. Without such changes, the regulations clearly go beyond the Department's authority and fails to recognize S. 25257.1's clear mandate that DTSC cannot supersede another agency's regulatory program.

Suggested Exemption language for PaintCare® and similar programs required by statute

The draft regulations require manufacturers of selected consumer products to "fund, establish, and maintain an end-of-life management program for the product." In 2010, legislation was passed in California establishing such a program for the paint industry. The program is called PaintCare®. Since PaintCare® is already established by statute, there is no reason for DTSC to subject the coatings industry to additional regulatory requirements in this area. ACA respectfully requests that DTSC include the following language in the regulations that specifically exempts PaintCare® and any other end-of-life management programs that are established by statute.

Amend S. 69506.8. (a):

(a) Except as provided in sections 69506.4 and 69506.8 (e), a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that both of the following requirements are met:

Add a new S. 69506.8 (e):

(e) A responsible entity otherwise subject to the requirements of this section shall be exempt from an end-of-life management regulatory response if the responsible entity is participating in an end-of-life management or extended producer responsibility program that is currently required pursuant to a different California statute or regulation.

Department Review of Claims of Trade Secret Protection (Section 69510.1)

ACA previously noted that the current draft of the regulations fails to fulfill the policy set forth in the CA Civil Code with respect to Confidential Business Information (CBI), and does not provide CBI for manufacturers. ACA suggested that the regulations focus on the interrelationship with preexisting California law on trade secrets. While there is the ability to assert a claim of trade secret protection with respect to documents or information submitted to the department, there are many documents and questions that will be requested by DTSC. The approval of CBI claims would be conditional based on DTSC's review. This overriding theme of manufacturers being subject to the whims of DTSC continues to be problematic. More than any other section, the CBI section must be clarified in order to adhere to the spirit and letter of the CA Civil Code on trade secret protection.

This trade secret section of the regulations should focus on the interrelationship between the new Safer Consumer Products Regulations and the preexisting California laws on trade secrets.

California Civil Code Section 3426.1:

(d) "Trade Secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process that:

- (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one should allow that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by DTSC under California Health and Safety Code Section 25257(d) should logically begin by looking at those two questions.

Another issue that arises relative to trade secrets is whether the information is readily ascertained by proper means (e.g. reverse engineering). If information can be readily determined through legitimate analysis or examination and study of a product, that information is probably not a trade secret.

Thus it would be reasonable to approach the question of supporting a claim of trade secrecy by asking the submitter to provide information relevant to items (1) and (2) above and relevant to the difficulty of discovering the information through analyzing the product. Much of the current draft regulation in Section 69510 is not needed in order to show that submitted information meets the definition of a trade secret under California law, and those items should not be required of the person (company) claiming the trade secret rights.

Further, given that under Section 69510(f) of the draft regulations trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient, there is no reason why the lengthy and intrusive list of questions in the draft regulations is

necessary. Answering all of those questions for each trade secret claimed will be a burden requiring needless expenditure of resources by trade secret owners, adding to the cost of consumer products.

It is worth pointing out that the California statute which the draft regulations purport to implement states in Section 25253(c):

(c) The department in developing the processes and regulations pursuant to this section shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

The current draft regulations fail to fulfill the aspiration set forth in the statute. In their treatment of trade secrets, they do not ensure a process that is easy to use, nor are they simplified tools that manufacturers, distributors, retailers, and consumers can use.



American Forest & Paper Association

October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Comments on the Safer Consumer Products Proposed Regulation, Dept. Ref. No. R-2011-02, Office of Administrative Law Notice File No. Z-2012-7017

Dear Ms. Von Burg:

On behalf of the American Forest & Paper Association (AF&PA), we respectfully submit the following comments to the California Department of Toxic Substances Control (DTSC) regarding the proposed Safer Consumer Products (SCP) draft regulations issued on July 27, 2012.

AF&PA is the national trade association representing pulp, paper, packaging and wood products manufacturers, and forest landowners. Our companies make products essential for everyday life from renewable and recyclable resources that sustain the environment. The forest products industry accounts for approximately 5 percent of the total U.S. manufacturing GDP. Industry companies produce about \$190 billion in products annually and employ nearly 900,000 people. The industry meets a payroll of approximately \$50 billion and is among the top 10 manufacturing sector employers in 47 states. In California, the paper industry employs nearly 23,000 individuals at 489 manufacturing facilities, meeting an annual payroll of over \$1.6 billion. The estimated state and local taxes paid by the forest products industry totals \$318 million annually.

AF&PA has worked with the Green Chemistry Alliance (GCA) in the last few years to provide the DTSC with data and expertise to assist in developing regulations that will lead to safer consumer products and avoid unnecessary obstacles and burdens to businesses. We appreciate the opportunity to highlight our concerns on recycled materials and food contact material at the DTSC public hearing held on September 10, 2012. We believe DTSC has made some positive revisions to the proposed regulation. However, we believe more changes are needed for this to be a viable program.

Appropriate Analysis on Environmental and Economic Impacts

AF&PA requests that DTSC complete a proper California Environmental Quality Act (CEQA) review before this regulation moves forward. In March 2008, DTSC issued a CEQA Notice of Exemption on the SCP (DTSC 1332 (03/04/08)). CEQA requires the state to follow a protocol of analysis and public disclosure of environmental impacts of proposed projects

and adopt all feasible measures to mitigate those impacts.¹ Contrary to what is claimed by DTSC in the Notice of Exemption, we believe the regulation could have a significant environmental impact. As we explain in more detail below, we believe the SCP could have a significant environmental impact, as it would create a disincentive for manufacturers to use recycled feedstock and could deter efforts to increase paper recovery in California. We believe DTSC has not used its best efforts to make a thorough investigation, instead suggesting that the CEQA review will be done at a later time “during implementation of the regulatory program.” The suggested future environmental review does not excuse DTSC’s requirement to adequately analyze the reasonably foreseeable significant environmental effects of the proposed regulations.

In addition, the DTSC’s Economic and Fiscal Impact Statement and Economic Analysis on the SCP is inadequate and lacking any substantive information about the real costs of the proposed regulations to California, consumers, or the regulated community. DTSC states that the economic and fiscal impact of the regulation is unknown and will be quantifiable only after the regulation is implemented and operating. The open-ended and undefined requirements that DTSC has included in the proposed regulations are unacceptable. It also is unacceptable for DTSC to finalize these regulations without knowing and understanding the actual cost of the regulations and the effect on businesses and jobs in California. We strongly recommend that the regulation be tailored to ensure that responsible party compliance with this program does not lead to excessively burdensome economic effects that could unintentionally result in perverse incentives for jobs to leave the state and for citizens to be deprived of safe and beneficial products that are legally marketed throughout the rest of the US.

On October 1, 2012, Senator Rubio and 15 Senate and Assembly members sent a letter to Governor Brown requesting that California withhold submission of the proposed regulations to the Office of Administrative Law until DTSC conducts an economic analysis that complies with the requirements set forth in the recently enacted SB 617 (2011). AF&PA agrees with Senator Rubio that this is not the economic climate to be crafting a regulation that has significant uncertainty on how it will effect businesses of all sizes and jobs in California. AF&PA requests the DTSC to conduct an economic analysis on the SCP that complies with the requirements in SB 617, and withhold the proposed regulations until that analysis is complete and stakeholders are given an opportunity to comment.

Scope of the Program

It ultimately is DTSC’s responsibility to strike the proper balance between the scope of the program and the resources available to achieve success. A program that takes on more than it can achieve is unsustainable and will produce little to advance public health and environmental protection.

We are pleased that the Department has chosen to focus the program initially by limiting the regulation to five Priority Products. We believe this is a practical approach that will enable the Department to steer the program, learn what works best, and make adjustments

¹ Public Resources Code Section 21080, 14 Cal. Code Regs Section 15357.

accordingly. However, the regulatory scheme DTSC has proposed still is in excess of what the initial phase should be, and far in excess of that which it has resources to support. We, in concurrence with the GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on risk, considering hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

One of the more concerning aspects of the proposed regulation is the discretion the Department gives itself to implement the program. The Department allows itself considerable discretion for decisions without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation.

Recycled Materials

We commend the DTSC staff for its efforts to revise these regulations so they are workable for businesses. Despite this work, the latest version of the SCP regulation largely ignores the input of those who design, manufacture and sell recycled content products in California, will deter efforts to increase paper recovery, and is out of step with regulatory approaches used in other states and internationally.

Paper recycling is one of the nation's great environmental success stories and AF&PA is a leader in promoting paper recovery and recycling. In 2011, a record-high 66.8 percent of the paper consumed in the U.S. was recovered for recycling. Paper and paperboard recovery has increased 81 percent between 1990 and 2011. Paper recycling reuses a renewable resource that sequesters carbon and helps reduce greenhouse gas emissions. In addition, in 2011 the amount of paper that was recovered for recycling saved 174 million cubic yards of landfill space.

In keeping with the forest products industry's legacy as a leader in sustainability, in 2011 AF&PA launched the *Better Practices, Better Planet 2020: Continuing AF&PA's Commitment to Sustainability* initiative. As part of this initiative, the industry has set a goal to further increase paper recovery for recycling to exceed 70 percent by 2020 and will work with communities, businesses, and schools to reach this goal.

The draft proposal explains that the DTSC may specify a higher alternative analysis threshold if the source of the chemical of concern is a "contaminant in recycled materials" and meets other criteria including the chemical "cannot reasonably be removed from the product." We appreciate that the proposal includes an option that the DTSC may ease the alternative analysis threshold level for recycled feedstock, but we are requesting an exemption for recycled feedstock to prevent a host of unintended consequences. These include unnecessary costs and burdens that will discourage manufacturing of products that use recycled feedstock without creating environmental or public health benefits, including increased compliance costs to detect even *de minimis* amounts of chemicals.

AF&PA is concerned this provision will impose a disproportionate burden on those who use recycled feedstock, will create a disincentive to using recycled feedstock, will decrease demand for recycled feedstock where virgin fiber is an alternative raw material and

will ultimately be counterproductive to recycling programs. Added costs to manufacturing of recycled content products created by this regulation could lead to more material being landfilled, and will hinder the state's ability to achieve its ambitious new 75 percent recovery goal by 2020. Exempting unintentionally added chemicals from the regulation's requirements is consistent with other state, federal and international chemical regulatory policies.

Regulatory Duplication – Exemption for Food Contact Materials

The statute is firm on the issue of regulatory duplication, stating that the Department should not supersede the authority of other agencies and that the Department shall not duplicate or adopt conflicting regulations for products already regulated.² It appears that this proposal goes beyond the statute to assert the Department can regulate a product if it believes it would provide a higher level of public health and environmental protection by regulating the product under the SCP. If the potential health or environmental impact from the chemical in the product is regulated by another agency, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

AF&PA requests a clear exclusion for food contact materials from the SCP. AF&PA believes that food contact materials are already fully regulated by a comprehensive federal regulatory schedule that ensures the safety of these materials for the public health and the environment throughout the full life cycle of the materials. Further regulation of these materials by DTSC under the Green Chemistry Initiative (GCI) would be duplicative and in conflict with the existing federal regulatory scheme. The GCI specifically prohibits regulatory duplication or conflict with existing or pending regulations of other Agencies that are consistent with the initiative's purposes. An additional layer of state regulation will inhibit technological innovation and the development of safer and more environmentally friendly food packaging materials, and, ultimately, could even force safe packaging materials out of the California market.

California should focus the SCP regulation on products not already subject to thorough regulations. Since the U.S. Food and Drug Administration's (FDA) regulatory system is already in place, the regulation would do nothing to further protect the public. According to DTSC's Initial Statement of Reasons, the GCI intends to address what it believes is a "structural weakness" in the federal Toxic Substances Control Act (TSCA). Further regulating food packaging which is already fully regulated by FDA will not achieve GCI's policy goals and is unlikely to result in safer consumer products.

The safe use of food contact materials (FCM) is not regulated by TSCA, but rather the Federal Food, Drug, and Cosmetic Act (FDCA). The FDCA provides for a robust regulatory structure to protect the safety of the public health and environment. The FDA employs more than 30 chemists, toxicologists, and other scientific staff, for the sole purpose of evaluating the safety and environmental impact of chemicals in FCMs. With all of the decades of experience this team has, it would be wasteful, from both a policy and resource perspective, for DTSC to attempt to duplicate this system. The GCI product mandate is broad, addressing almost all consumer products on the market. Thus, considering the scientific and technical

² GCI Section 25257.1(c) states, "The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

complexity of evaluating FCMs, DTSC should defer to the reasoned and scientific judgment of FDA.

One of the reports that helped shape the underlying policies to GCI was *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*.³ The report identified three information gaps in federal chemical policy: (1) a data gap, based on a lack of information on which chemicals are safe and what products contain them; (2) a safety gap, based on the rationale that government agencies do not have the legal tools or information to prioritize chemical hazards; and (3) a technology gap, which supposedly results in a lack of emphasis in industry on green chemistry principles. These gaps were connected to gaps in health and environmental damage occurring in California. The simple fact is that these weaknesses and information gaps do not apply to food contact materials (FCMs). Regulations by FDA require food contact materials manufacturers to ensure the safety of their products for the public health and environment *before* placing the product on the market. This premarket evaluation ensures that the gaps—data, safety, and technology—identified in the *Green Chemistry* report are not applicable to FCMs.

Rigorous premarket evaluation ensures that substantial amounts of data are available on FCMs and their potential exposure to the public and the environment. Modern food packaging is carefully designed to preserve the quality and safety of the food and extend the shelf life of products, preventing food waste. Other consumer products covered by the GCI are inherently designed to contact the consumer or the environment, resulting in direct exposures that are substantially higher exposures than to any food contact substance. The FDA is fully aware of the potential uses of FCMs and, if the Agency became aware that a particular use of a chemical was unsafe, could take regulatory action to remove the substance from the market.

A technology gap does not exist for FCMs because the industry is highly active in producing green, sustainable materials. The recycling of FCMs has long been of interest for materials such as paper. FDA reviews recycling processes to ensure that any substances that may be present in the source material of a recycling stream do not contaminate the finished product or make it unsafe for use. Products are constantly being developed that are biodegradable, compostable, or are manufactured using renewable and sustainable raw materials. Of course an existing regulatory framework ensures these new materials are safe for their use. The SCP would subject innovative and beneficial FCMs to multiple regulatory schemes, delaying the arrival of such materials to the market and possibly precluding their manufacture altogether because of the increase in regulatory costs.

We believe if DTSC attempts to duplicate FDA's regulatory framework it could result in product deselection rather than extensive analysis of chemical alternatives and is unlikely to help consumers understand the complex scientific analysis that goes into a safety evaluation for a food contact material. FCMs are designed specifically to ensure the safety of food for the entire shelf-life of a product, and reformulation could impact the efficacy of a product,

³ Wilson M.P., Chia D.A., Ehlers B.C., "Green chemistry in California: a framework for leadership in chemicals policy and innovation," 2006, available at <http://coeh.berkeley.edu/FINALgreenchemistryrpt.pdf>.

potentially resulting in an increase of foodborne illness. Yet the use of a Chemical of Concern in an individual food packaging product may be extremely small, without any reasonable possibility for the substance to become part of food or have consumer/environmental exposure. Thus, many FCMs, the safety of which has already been established under the existing FDA framework, could be forced out of the California market due solely to the presence of one Chemical of Concern.

In summary, FDA has placed a comprehensive regulation for food contact materials that establish a large margin of safety. The SCP would duplicate this system, yet FDA's regulatory scheme is consistent with the purposes of SCP. Thus, the inclusion of these products in the SCP would contravene the limitations proscribed by Section 25257.1(c) of the Health and Safety Code and would not promote the safety or environmental goals of the GCI.

Interstate Commerce

AF&PA objects to the proposed regulations because they would impose significant burdens on businesses that import their products into California. We believe these burdens vastly outweigh any alleged benefit of the regulations. The regulations impose burdens on the import of goods into California by requiring a detailed analysis of the contents of the products as well as the manner in which these products were produced and transported to California. DTSC acknowledges that “[r]esponsible entities will bear real costs as a result of these regulations,” but that “[s]ince most product manufacturing takes place outside California,” the expected “California employment impacts [would] be minimal.”⁴ DTSC has adopted the view that “California firms have an edge in gaining . . . market share” for developing “greener alternatives” under the regulations.⁵ According to DTSC, the regulations establish “new ‘rules of the game’” governing the import of products in California. Under these “new rules,” “California’s firms are likely to [be] among the most nimble in responding and thriving in the new regulatory environment.”⁶ California does not have authority to set the “rules of the game” governing the interstate and international market for consumer goods sold in California in a manner designed to benefit California economic interests.

The regulations should not be adopted because they impose substantial barriers to the California market. These regulations allow DTSC to take over the decisions of California consumers and authorize DTSC to decide whether or not products – including safe products – can be marketed in California including, for example, the way in which they are manufactured outside California. See *Economic Analysis*, page 9 (acknowledging that some products “are likely to be banned”). The regulations authorize DTSC to deny California residents the opportunity to decide whether to purchase a product based on DTSC’s assessment of the manner in which the product was produced or whether another means of production would render a competing product economically feasible. These regulations impose significant costs on manufacturers that must bear the burden of testing their products,

⁴ Matthew E. Kahn, *Economic Analysis of California’s Green Chemistry Regulations for Safer Consumer Products*, at 4, 5 (Mar. 2012) (“*Economic Analysis*”).

⁵ *Id.*, p 5.

⁶ *Id.*, p 9.

conducting alternative analyses, and then complying with the regulatory response dictated by DTSC. These barriers are especially harmful to small businesses that lack the resources to comply with these burdensome regulations.

In contrast, there are limited, if any, benefits from the regulations. Chemical ingredients in consumer products already are subject to regulation at the national level by TSCA administered by US EPA and the Federal Hazardous Substances Act as well as other statutes administered by the Consumer Product Safety Commission. In addition to these uniform federal regulations, manufacturers already have strong incentives to ensure that their products are safe and effective both by market mechanisms through which consumers, presented with a choice, will purchase products with safer ingredients as well as remedies to consumers injured by products that are actually unsafe. The proposed regulation seeks to replace these existing protections and informed consumer choice with local government mandates. Indeed, DTSC has not demonstrated that the burdens imposed by the regulations justify the substantial costs and burdens that DTSC acknowledges that would be imposed on importers of products into the California market.

We respectfully ask you to re-examine this process before these regulations move further toward completion to ensure that California's green chemistry regulations will enhance safety, rather than add needless costs and obstacles to manufacturers doing business in California.

We appreciate the opportunity to comment on the proposed Safer Consumer Products regulation. If you have any questions regarding AF&PA's position on the proposal, please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202.

Sincerely,



Paul Noe
Vice President, Public Policy
American Forest & Paper Association

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor
Kathy Lynch, Lynch Associates



October 11, 2012

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Comments on the Safer Consumer Products Proposed Regulation, Dept. Ref. No. R-2011-02, Office of Administrative Law Notice File No. Z-2012-7017

Dear Ms. Von Burg:

On behalf of the American Wood Council (AWC), we respectfully submit the following comments on the California Department of Toxic Substances Control (DTSC) regarding the proposed Safer Consumer Products (SCP) draft regulations issued July 27, 2012.

AWC is the voice of North American traditional and engineered wood products, representing over 60 percent of the industry. From a renewable resource that absorbs and sequesters carbon, the wood products industry makes products that are essential to everyday life and employs about one-third of a million men and women in well-paying jobs. AWC's engineers, technologists, scientists, and building code experts develop state-of-the-art engineering data, technology, and standards on structural wood products for use by design professionals, building officials, and wood products manufacturers to assure the safe and efficient design and use of wood structural components. AWC also provides technical, legal, and economic information on wood design, green building, and manufacturing environmental regulations advocating for balanced government policies that sustain the wood products industry. In California, the wood products industry employs over 26,000 individuals at 66 manufacturing facilities, meeting an annual payroll of nearly \$1.2 billion.

Economic Impact Analysis

DTSC's Economic and Fiscal Impact Statement and Economic Analysis on the SCP is inadequate and lacking any substantive information about the real costs of the proposed regulations to California, consumers, or the regulated community. DTSC states that the economic and fiscal impact of the regulation is unknown and will be quantifiable only after the

regulation is implemented and operating. The open-ended and undefined requirements that DTSC has included in the proposed regulations are unacceptable. It also is unacceptable for DTSC to finalize these regulations without knowing and understanding the actual cost of the regulations and the effect on businesses and jobs in California.

On October 1, 2012, Senator Rubio and 15 Senate and Assembly members sent a letter to Governor Brown requesting that California withhold submission of the proposed regulations to the Office of Administrative Law until DTSC conducts an economic analysis that complies with the requirements set forth in the recently enacted SB 617 (2011). AWC agrees with Senator Rubio that this is not the economic climate to be crafting a regulation that has significant uncertainty on how it will affect businesses of all sizes and jobs in California. AWC requests the DTSC to conduct an economic analysis on the SCP that complies with the requirements in SB 617, and withhold the proposed regulations until that analysis is complete and stakeholders are given an opportunity to comment.

Scope of the Program

We are pleased that the Department has chosen to focus the program initially by limiting the regulation to five Priority Products. We believe this is a practical approach that will enable the Department to steer this program and to learn what works best and make adjustments accordingly. However, the regulatory scheme DTSC has proposed is still in excess of what the initial phase should be, and far in excess of that which its own resources can support. We, in concurrence with the Green Chemistry Alliance (GCA), strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

We strongly recommend that the regulation be tailored to ensure that responsible party compliance with this program does not lead to excessively burdensome economic impacts that could unintentionally result in perverse incentives for jobs to leave the state and for citizens to be deprived of safe and beneficial products that are legally marketed throughout the rest of the US. It is ultimately DTSC's responsibility to strike the proper balance between the scope of the program and the resources available in order to achieve success. A program that takes on more than it can achieve is unsustainable and will produce little to advance public health and environmental protection.

One of the more concerning aspects of the proposed regulation is the discretion the Department gives itself to implement the program. The Department allows itself considerable discretion for decisions without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-inclusive program that appears to exceed the more modest intent of a practical approach. It seems that the latest proposal will encompass virtually all commercially available products and their packaging, not simply common everyday consumer products.

Definition of Chemical

The DTSC defines “chemical” as “organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or part, as a result of a chemical reaction or occurring in nature, and any element or uncombined radical.” The definition of chemical should exclude natural products that are not chemically altered such as wood in lumber products.

Regulatory Duplication

The statute is firm on the issue of regulatory duplication, stating that the Department should not supersede the authority of other agencies and that the Department shall not duplicate or adopt conflicting regulations for products already regulated.¹ However, it seems that the proposal goes beyond the statute to assert the Department can regulate a product if it believes it would provide a higher level of public health and environmental protection by regulating the product under the SCP. The Department should take a straightforward unambiguous approach to that question. If the potential health or environmental impact from the chemical in the product is regulated by another agency, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

AWC is extremely concerned by the references the DTSC staff has made to formaldehyde-containing products as examples of priority products. It would be inappropriate to list composite wood made with resins containing formaldehyde as a priority product since it would duplicate regulation under the California Air Resources Board’s (CARB) Composite Wood Products Airborne Toxic Control Measure which is intended to reduce formaldehyde emissions from composite wood products including hardwood plywood, particleboard, medium density fiberboard, thin medium density fiberboard, and furniture and other finished products made with composite wood products. Further, in 2010 Congress passed the Formaldehyde Standards for Composite Wood Products Act which establishes national formaldehyde emission standards for composite panel products based on California’s technology-based standards. In fact, the U.S. industry is already meeting those standards, which are the most stringent in the world. Further regulation of composite wood products under SCP would be regulatory duplication, which is prohibited by the statute.

We respectfully ask you to re-examine this process before these regulations move further toward completion to ensure that California's green chemistry regulations will enhance safety, rather than add needless costs and obstacles to manufacturers doing business in California.

¹ GCI Section 25257.1(c) states, “The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.”

We appreciate the opportunity to comment on the proposed Safer Consumer Products regulation. If you have any questions regarding AWC's position on the proposal, please contact Laurie Holmes at (202) 463-5174 or Kathy Lynch at (916) 443-0202.

Sincerely,

A handwritten signature in black ink that reads "Robert W. Glowinski". The signature is written in a cursive style with a small flourish at the end.

Robert Glowinski
President
American Wood Council

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor
Kathy Lynch, Lynch Associates

7575 FULTON STREET EAST
ADA, MICHIGAN 49355-0001

www.amway.com



October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
(via e-mail: gcreqs@dtsc.ca.gov)

Dear Ms. Von Burg

Amway would like to express sincere concern regarding the Proposed *Safer Consumer Products* Regulations released for comment on July 27, 2012 by the California Department of Toxic Substances Control (DTSC). While we do very much appreciate the extension given in the comment period, our company believes strongly that the regulatory process outlined misses a real opportunity to advance the goals set out in the enabling legislation. This is particularly disturbing in light of the effort made by our company and many others in industry to support and inform the process of developing these regulations.

Amway is a global business with \$10.9 billion in sales. The Access Business Group, the operations component that supports Amway independent business owners (IBOs) with products, is engaged in the development, production and distribution of a wide variety of consumer products. Our company has manufacturing facilities in California and supports tens of thousands of small businesses selling our products in the state. Because of our commitment to California business and to the health and safety of California consumers and environment, we have been pleased to actively engage the California Legislature and DTSC to support and improve the Green Chemistry Initiative. Our comments to the earlier, informal proposals did identify both points of agreement and suggested corrections. We continue to support the intent of the legislation and the effort of DTSC to draft meaningful rules. The comments below are made in the same constructive spirit although we will limit ourselves to focus on the needs we see for improvement.

Chemicals of Concern Identification Process

As written, the proposed regulations would develop a list of Chemicals of Concern (CoC) derived from 22 lists from various government bodies. The Department has estimated that this "List-of-Lists" approach will result in

identifying approximately 1,200 chemicals. This is inconsistent with a review by the Green Chemistry Alliance which enumerated over 4,000 chemicals that are detailed in the subject lists. This results in a continuing confusion over the process by which CoC are ultimately identified.

Moreover, the approach taken by DTSC fails to meet the statutory mandate to prioritize chemicals of concern. The various lists are certainly appropriate as a pool from which to identify candidate chemicals. However, citizens of the state and those companies subject to the alternatives assessment process deserve clear criteria for selection of the highest priority concerns. Ideally, this would be accompanied by a screening process to select those chemicals and products for which action would be taken.

Focusing attention on a limited number of high priority programs is clearly appropriate since DTSC has acknowledged that only a few alternative assessments can be performed initially. The current framework does not give assurance that resources are being directed toward a highest priority item, only one of over one thousand possibilities.

Consumer Product Prioritization Process

The process to identify and list Priority Products is still unclear which leads to further uncertainty in establishing clear priorities for the program. The Initial Statement of Reason (ISOR) states that there will be a two-fold evaluation but DTSC performs the evaluation by a private assessment rather than one transparent to scrutiny. By contrast the prioritization of product selection should be a predictably open as the alternatives assessment to the Department expects to hold the subject companies. .

Allowance for Contaminants

The proposed regulations do not make a distinction between intentionally-added ingredients and incidental contaminants. Treating the incidental presence of a substance with the same rigor as purposeful addition will frequently misdirect the energy of manufacturers toward performance of AAs that are of low or no value and defeat the purpose of the program. There may be some rare occasion of high hazard but these instances have typically been managed by other programs of ingredient restriction.

Other regulations provide for such an allowance, e.g. Washington State's Children's Safe Products Act. In that regulation *intentionally added chemical* is distinguished from a *contaminant*. DTSC would be wise to adopt the same distinction and deal with ingredient purity in a separate evaluation for priority.

Risk for Small and Medium-sized Enterprises (SMEs)

The Alternatives Assessment requirements established by the Department and the threat of regulatory intervention are unnecessarily restrictive for smaller companies. Even if larger companies are able to adapt to the proposed requirements, SMEs could find themselves overwhelmed by the number of their

ingredients and products subject to this regulation. DTSC should consider the effect on SMEs and recognize that these businesses are likely to provide innovative solutions and stable employment if they are not pressured by multiple requirements and short response time frames. If they are given relief from some AA requirements, these companies can be a great resource for Green Chemistry program success and a boost to the California economy.

Conclusion

In addition to the comments outlined above, Amway would like to see DTSC address the lack of any meaningful encouragement of voluntary product improvements. As currently written, the proposed regulation would reward companies delay until required to perform the AA. If DTSC were to provide some compensatory advantage, regulatory relief for example, to early implementation, there might be more innovation unleashed in an effort to reduce likely priority CoCs in higher priority product categories.

We continue to be supportive of the intent of the Green Chemistry Initiative but believe that the current regulatory proposal is very unlikely to deliver the benefits foreseen by the coalition that had endorsed that concept.

Respectfully submitted,

Robert W. Hamilton
Regulatory Policy Director
Amway



**THE ART & CREATIVE
MATERIALS INSTITUTE, INC.**
99 Derby St., Suite 200
Hingham, MA 02043 USA
Tel. (781) 556-1044 Fax (781) 207-5550
Website: www.acminet.org

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Products Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812 - 0806

Re: Safer Consumer Products Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z - 2012 - 0717 - 04) (July 2012)

Dear Ms. Von Burg:

On behalf of The Art and Creative Materials Institute, Inc. ("ACMI"), the following Comments are submitted regarding the Department of Toxic Substances Control's ("DTSC") proposed Safer Consumer Products Alternatives Regulation of July 2012.

The New Proposed Regulations:

The proposed regulations have a staggering complexity. Many small manufacturer members will probably file notices with DTSC under Section 69501.2 (b) to withdraw products from the stream of commerce in California for products that may contain chemicals to be regulated by DTSC. Small companies are unable to finance the kind of regulatory compliance required by the proposed regulations.

Product performance sustainability is ignored in the substitution process. Ingredients are chosen and tested for years by manufacturers to be compatible with all ingredients and components to prevent product failure and sustain maximum product performance and life to the end user. The proposed regulations ignore special requirements in engineering elements of a product and specialized personnel required for each specific product. The proposal does not take into account that while a chemical may seem the same it take years of testing to confirm that product failure will not result from interaction with a substitution. In effect, the proposed regulations rob the individual companies of the right to use their skilled personnel to fairly evaluate in a timely fashion the impact that may occur if the substitution fails.

LOOK FOR THESE SEALS.....



Moreover, no art material manufacturer can afford the expense of the DTSC process to find an alternative for a product with a limited customer base, when these same companies have sought to discover alternatives for more than a century that will satisfy the demands of some professional artists or restorationists.

An exemption for products with listed chemicals for which there are no known substitutes should be provided in the regulations. Similar exemptions are being sought for historic products for repair and other purposes. At least for art materials, the products are labeled for acute and chronic health hazards in compliance with federal law. The expert analysis required to be performed under the FHSA and the LHAMA amendment to the FHSA is in itself not inexpensive for existing product ranges. A similar analysis for environmental hazard is likely to exceed that cost by a factor of ten.

De Minimis Defaults and Related Issues:

The current proposed regulations have no minimal default levels for contaminants or trace amounts of toxic chemicals that may be detected in products. On October 1, 2012, the Federal Trade Commission ("FTC") published its revised Green Guides on the FTC website, a guide for marketers using "green claims". Even the FTC, while declining to issue default levels, stated in the Statement of Basis and Purpose at page 148:

"However, a non-toxic product could contain a toxic substance at a level that is not harmful to humans or the environment. For example, apple seeds contain cyanide. Although a marketer could not claim that cyanide is non-toxic, the amount in an apple is so low that it is not harmful to humans or the environment and so the marketer could claim the apple is non-toxic."

DTSC must establish levels for which contaminants or trace amounts are permitted in products in Section 69501.1 and provide in advance an example relevant to the chemical under review.

Inaccessible Component:

An inaccessible component needs to be defined. If there is no exposure to a harmful or toxic chemical, there is no threat to human health or the environment in any meaningful way. The regulations of the CPSC provide a ready reference for DTSC to emulate.

Highly Durable Product:

Some art materials may be considered highly durable products. Once applied, they may last for centuries. A visit to any museum will confirm this claim.

Trade Secrets:

The proposed regulations fail to provide the protections to be afforded to trade secrets. Trade secrets are protected under both federal and state law. These regulatory short-comings have been addressed by other commenters and ACMI joins with these comments that assert that trade secret protections are not sufficiently addressed in the proposed regulations.

The 1200 Chemicals List:

The failure to publish the chemical list of 1200 Chemicals of Concern (CofC) is a total failure of transparency in the regulatory process. If there is currently a list of the 1200 CofCs within DTSC's possession or control, it should be released now.

Economic Impact Analysis:

There has been no economic impact analysis by DTSC as required by the statutory underpinnings of the regulations. There certainly has been no Economic Impact Analysis of the impact upon the art materials industry of this proposed regulatory scheme and none for other industries large and small.

Nor has there been any analysis of the health and environmental benefits of this regulatory scheme within the State of California to justify such an expensive and complex regulatory scheme.

It is respectfully submitted that the promulgation of these proposed regulations, in the face of current economic conditions, will severely impact manufacturers located within and outside California. The proposed regulations will also limit product availability in California, to the detriment of California consumers.

Background of Commenter:

ACMI is an international trade association of the art materials industry with over 220 member manufacturers and distributors worldwide, who manufacture and/or distribute art materials throughout the United States. We estimate that approximately 13% of our members' sales are in California, a State known for a lively and diverse artist community.

In 1988, ACMI co-sponsored with the U.S. Public Interest Group, the federal Labeling of Hazardous Art Materials Act ("LHAMA"), the first federal legislation to require chronic health hazard labeling for art materials. Acute health hazards had previously been regulated by the Consumer Product Safety Commission ("CPSC") under the Federal Hazardous Substances Act ("FHSA"), but chronic hazards were not regulated. As a result of the enactment of LHAMA, CPSC subsequently issued Chronic Hazard Guidelines and published a new definition of chronic toxicity under the FHSA.

In California, ACMI has cooperated with OEHHA, which annually publishes a list of art materials that under California law may not be purchased by schools for use in grades K – 12. OEHHA has for years used, with ACMI's permission, its "CL List", a list of art materials with acute or chronic health or other hazards – not suitable for use by children. ACMI also certifies an "AP List" of art materials that are non-toxic or safe for children's or adult use. The overwhelming number of products certified by ACMI in its Certification Program are non-toxic or safe for all consumers. Over 60,000 products have been certified by ACMI since the inception of its certification program.

ACMI's toxicological resources consist of toxicologists at the Duke University Medical Center, who review complete formulation information and require such tests of products as may be required for compliance with the laws and regulations that affect them.

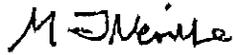
ACMI's membership worldwide is composed primarily of small business manufacturers, who do not have in-house toxicological resources.

Thank you for this opportunity to present the views of the art materials industry on the new proposed regulations.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David H. Baker', with a long horizontal stroke extending to the right.

David H. Baker
Executive Director

A handwritten signature in black ink, appearing to read 'M. J. Neville', written in a cursive style.

Martin J. Neville, Esquire
Of Counsel

October 10, 2012

Deborah Raphael
Director
Department of Toxic Substances Control
1001 "I" Street
Sacramento, CA 95812

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)
(Submitted Via Email)**

To Ms. Raphael:

The Technical Affairs Committee of the Association of Global Automakers, Inc.¹ (Global Automakers) appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) on the Draft Regulations of Safer Consumer Products, released on July 27th, 2012.

Global Automakers and its members have consistently supported the development and use of safe chemicals and products available for use in the automotive industry. Through the application of green chemistry principles and sound scientific methods, Global Automakers believes that the design and development of new chemistries and technologies will continue to provide innovative solutions to current and emerging environmental challenges. Our goal is to ensure that our members have the opportunity to provide high quality, environmentally sound, safe products and services. With these goals in mind, we look for ways to provide tools to our members to facilitate continuous improvement and to ensure that wherever possible we assist them to not only meet but exceed safety and environmental standards.

Global Automakers has been actively engaged in the development of the Safer Consumer Products (SCP) regulations from the outset of this effort. Beginning in 2010, we have invested in review and comment for each of the iterations of these regulations; we have participated in public meetings and listened intently to

¹ The Association of Global Automakers represents international motor vehicle manufacturers, original equipment suppliers, and other automotive-related trade associations. Our Technical Affairs Committee members include: American Honda Motor Co., American Suzuki Motor Corp., Aston Martin Lagonda of North America, Inc., Ferrari North America, Inc., Hyundai Motor America, Isuzu Motors America, Inc., Kia Motors America, Inc., Maserati North America, Inc., McLaren Automotive Ltd., Nissan North America, Inc. Peugeot Motors of America Subaru of America, Inc., ADVICS North America, Inc., Delphi Corporation, Denso International America, Inc., and Robert Bosch Corporation. We work with industry leaders, legislators, and regulators in the United States to create public policies that improve motor vehicle safety, encourage technological innovation, and protect our planet. Our goal is to foster an open and competitive automotive marketplace that encourages investment, job growth, and development of vehicles that can enhance Americans' quality of life. For more information, visit www.globalautomakers.org.

the debates and discussions of the Green Ribbon Science Panels. We have appreciated the opportunity to meet with DTSC to provide constructive recommendations for areas of interest to us.

Global Automakers recognizes that DTSC has been working diligently to balance the requirements of AB 1879 and SB 509, as well as the input from a wide variety of interested and important stakeholders. We would like to recognize the considerable progress that has been made in a number of areas but also believe that as currently drafted, the regulations may create an unworkable system resulting in unintended chemical and/or product substitutions and misdirected resource investments in low rather than high priority areas.

Wherever possible we have commented on specific provisions of the regulations and tried to offer alternative strategies that Global Automakers believes will make these regulations more workable not only for the regulated community but for DTSC and the public as well. We recognize the enormity of the task at hand and would like to make clear that we support the overarching goals of the law and regulations. It is with that same goal in mind that we offer the following comments and recommendations.

Global Automakers thanks you for consideration of these comments and would welcome the opportunity to provide any additional information you may need. If you have any questions, please contact Julia Rege, Senior Manager, Environment & Energy at jrege@globalautomakers.org or (202) 650-5559.

Sincerely,



Michael J. Stanton
President & CEO, Global Automakers

CC: Odette Madriago, DTSC Deputy Director
Krysia Von Burg, Safer Consumer Product Alternatives Regulation Coordinator

**Comments submitted by
The Association of Global Automakers**

**Regarding the Proposal for
Division 4.5, Title 22, California Code of Regulations
Chapter 55. Safer Consumer Products Regulations (R-2011-02, July 2012)**

On July 27, 2012, the California Department of Toxic Substances Control (“DTSC” or “Department”) proposed the Safer Consumer Products (SCP) Regulations, which would require the manufacturers of certain chemical and product combinations to assess the relative hazards, exposures and functionality of available alternatives and through a comparative assessment process, select alternatives, when appropriate, that demonstrate a safer environmental profile. This proposal represents the eighth version in the development of these regulations. Throughout the pre-proposal stage, the Association of Global Automakers, Inc. (Global Automakers) has filed comment and provided other feedback on each version. While we continue to believe that the breadth of consumer products allotted under the guiding statutes (AB 1879 and SB 509) did not appropriately consider the differences between product types, we also recognize that, if DTSC moves forward with its current intent to include the components of motor vehicles and other complex durable goods² in these regulations, we need to provide input now to ensure the regulations provide the maximum degree of clarity, consistency, and flexibility.³ We remain concerned that the proposed regulations create an unworkable regulatory scheme for complex durable goods. At the November 2011 Green Ribbon Science Panel (GRSP) meeting, DTSC reiterated that these regulations need to be meaningful, practical and legally defensible, as they will set the precedent for the rest of the country. We cannot agree more and, in that spirit, offer these comments and recommendations.

Global Automakers represents 13 international motor vehicle manufacturers, as well as certain original equipment suppliers and automotive-related trade associations. Most of our motor vehicle manufacturer members not only sell their products in the United States but also design and manufacture them here, including the ground up work for designing or redesigning motor vehicles;

²From the proposed regulations, § 69503.4 Priority Products List, a “highly durable product,” or complex durable goods as we refer to it, means:

For purposes of subparagraph 2., “highly durable product” means a product that meets all of the following criteria:

- a. The product is assembled from 100 or more manufactured components;*
- b. Manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five (5) or more years; and*
- c. The product is typically not consumed, destroyed, or discarded after a single use.*

³ Global Automakers along with the Alliance believe light-duty automobiles should be excluded from the definition of manufacturers subject to the SCP regulations, as reflected in the letter of October 8, 2012 sent to Governor Brown, California EPA and DTSC. However, if the agency decides not to do so, Global Automakers hopes DTSC will give these comments and the concerns expressed therein its serious attention.

the manufacture of vehicles' components, body, frame, engines, and other aspects needed to assemble a vehicle; the assembly of vehicles; and the import and export of both components and whole vehicles in the United States. Our members have invested \$40.2 billion in U.S. operations, including 300 facilities and 82,000 jobs for Americans with an annual payroll of \$6 billion. To question the overall basis for our concerns about these regulations is perplexing since the automakers will not only be bringing the end product into California for sale but must work throughout the supply chain to ensure that the vehicle complies with any regulatory requirements. We believe there has been some misunderstanding that we are only assemblers, demonstrating the challenges that complex durable goods will face in meeting California's SCP regulations.

Although our comments are focused on the fundamental technical problems with the regulations that still remain, Global Automakers would like to recognize the efforts that DTSC has put into attempting to balance the various views and perspectives of all stakeholders, including the following positive developments:

- DTSC's decision to have an initial focus on no more than five product-chemical combinations and seven hazard endpoints. This decision is a sound policy step that will allow both DTSC and the regulated community to "learn by doing" without being overwhelmed by a large list.
- Development and issuance of a Priority Product Work plan by January 2014 that identifies potential product categories that will be under consideration during the next three year period.
- Augmenting the petition process to allow petitions for removal of chemicals.
- Allowing for a Chemical of Concern Removal Notification in lieu of an Alternative Analyses if the only change to a product is the removal of the Chemical of Concern.
- Removal of the inventory recall requirement from the regulatory response options.
- DTSC's commitment to provide guidance for the Alternative Assessment process beyond the regulations – this guidance will be essential for meaningful compliance.

Global Automakers also would like to thank DTSC for the opportunity to present our views during an October 4, 2012 teleconference with Global Automakers. During that meeting, DTSC reiterated that the SCP regulations will only be "forward looking," not to regulate products (or components) manufactured and placed in the stream of commerce in California prior to the implementation date for any selected regulatory control option. As a general overarching theme, this concept is important to recognize; as a regulatory principle, it is critical to understanding and defining the scope of the regulations and those products which fall under regulatory jurisdiction and those that do not.

Our comments focus on eight major areas of concern and provide suggested regulatory text where appropriate.⁴ While in the past, we have addressed the overarching principles of the regulation, such as the chemical of concern list, the prioritization process, etc., these comments are focused on the technical details that we believe are critical to the ability of automakers and the manufacturers of components contained within such products, to comply with the SCP regulations.

- A. §69501.1(a)(22)(B) Replacement Parts
- B. §69503.5 Alternative Analysis Threshold
- C. §69501.1(a)(21) Component
- D. Lead Time Requirements for Implementing Changes in the Automotive Sector
- E. §69503.3(b) Other Regulatory Programs
- F. §69506.8 End of Life Management Requirements
- G. §69501.1 Unintentionally Added Chemicals and Chemicals with no Exposure Pathway
- H. Compliance and Enforcement
- I. Compliance with CEQA
- J. APA Requirements

A. §69501.1(a)(22)(B) Replacement Parts

§69501.1(a)(22)(B)1. *“Consumer Product” or “Product” does not mean any historic product...*

§69501.1(a)(22)(B)2. *“Historic Product” means a product that ceased to be manufactured prior to the date the product is listed as a Priority Product.*

Ensuring that DTSC include a specific exemption for replacement parts is our highest priority issue and is absolutely necessary for ensuring the workability of this regulation for automobiles. Global Automakers has consistently commented to DTSC on the need to exclude replacement parts (including service, repair and legacy) from the purview of the SCP regulations. We have explained the impact on our fundamental business model and processes, as well as the deleterious effect on consumers.

Based on DTSC’s comments during our October 4, 2012 teleconference, we believe the Department agrees with our position that replacement parts manufactured prior to the implementation date of any regulatory response should be exempt from these regulations and that the regulations will be

⁴ In addition to our written comments, we adopt the comments submitted by the Durable Goods Coalition, the comments on the CEQA analysis submitted by the Alliance of Automobile Manufacturers, and “The Consumer Impact of California’s Green Chemistry Initiative” report from the California Foundation for Commerce and Education by reference.

“forward-looking.”⁵ As currently written in this latest proposal, however, that exemption is neither clear nor comprehensive, and we request that DTSC explicitly address this in the regulations going forward.

In DTSC’s July 2012 Initial Statement of Reasons (ISOR), DTSC notes that “existing products, especially durable goods, may need to have replacement parts available for service, repair and maintenance” (ISOR, p. 28) and suggests that the intent of the regulations is not to cause a consumer to replace existing items by regulating replacement parts. By allowing these exclusions, the service, repair, and maintenance of existing products can continue without the involvement of the regulatory program. The ISOR continues with examples that clearly highlight that all replacement parts – regardless of when they are manufactured - should be excluded. DTSC’s language in the ISOR demonstrates an understanding of the need for replacement parts and the appropriateness of excluding replacement parts for existing, or historic, products. DTSC’s articulation of the need for and practicality of such an exemption is wholly consistent with the “Repair as Produced” approach adopted by the European Commission (EC) for the End of Life Vehicle (ELV) Directive. Global Automakers reiterates our request that DTSC adopt a similar, straightforward exemption based on the EC’s “Repair as Produced” approach; Global Automakers has recommended this approach in our previously submitted written comments (July, 2010; October, 2010; December, 2011) and during discussions with DTSC. Specifically, the ELV language is as follows:

In certain cases it is technically impossible to repair vehicles with spare parts other than original ones as this would require changes in dimensional and functional properties of entire vehicle systems. Such spare parts cannot fit into the vehicle systems originally manufactured with parts [containing heavy metals] and these vehicles cannot be repaired and may need to be prematurely disposed of. Annex II to Directive 2000/53/EC should therefore be amended to enable the repair of such vehicles. (Commission Directive 2011/37/EU, March 30, 2011)

In the proposed SCP regulations, DTSC’s proposed definition of “Historic Product” does not include a specific exemption for replacement parts. Including a clear and comprehensive exemption for replacement parts in the regulatory text is critical to establishing that replacement parts are not subject to these regulations since the regulations, not the ISOR, are the basis for compliance. Replacement parts are not only needed to repair products, such as automobiles, but to also ensure that any such repair will meet continued safety, performance, serviceability and reliability requirements. Consumers purchase

⁵On an October 4, 2012 teleconference with DTSC, Global Automakers discussed the need for an explicit exemption for replacement parts in the regulations, and DTSC clarified that it was not their intent to cover replacement parts made prior to any adopted regulatory response. While DTSC believed that the currently proposed definition of historic product combined with the exclusions for repair and refurbishment under the definition of manufacturer adequately exempted replacement parts, Global Automakers explained that the regulatory language related to the exemption was not as clear and as comprehensive as needed. Based on our October 4th meeting with DTSC, we believe that we are in agreement that replacement parts manufactured prior to the implementation date of any regulatory response should be exempt from these regulations.

cars with the expectation that they will be able to repair or replace any necessary components over the lifetime of the vehicle.

In addition, §69501.1(a)(40) of the proposal defines manufacture to mean “to make, produce, or assemble” and excludes from the definition repair, refurbishment, installation of standardized components, and alterations. It would follow that replacement parts needed to support the repair and refurbishment of automobiles would also be exempt from the scope of these regulations, but again, this point is not explicitly stated in the proposed rule.

In addition to adding specificity excluding replacement parts from the “Historic Product” definition, the proposal needs to clarify the status of products manufactured and entering the stream of commerce between the Priority Product listing date and the implementation date of the regulatory response. The current “Historic Product” definition limits the exemption to products “manufactured prior to the date the product is listed as a priority product.” As a consequence, the regulations are silent and could be read to cover replacement parts if the replacement parts are (1) manufactured between the listing of a priority product and the completion of the regulatory response process or (2) manufactured after the regulatory response process in order to repair a historic product as produced. This situation is problematic for a number of reasons.

Based on the proposed definition of “Historic Product” and the following example, our concerns are as follows:

EXAMPLE*: On January 31, 2012, DTSC lists copper in brake assemblies as a Chemical of Concern / Priority Product. The Alternative Analysis and Regulatory Response process are completed by December 1, 2015. The regulatory response requires that copper be replaced with an alternate friction material by June, 2016.

Between January 31, 2012 and December, 1, 2015 automobiles continue to be manufactured with copper in their brake assemblies because no alternatives have been identified, and there is no agreed upon regulatory response. Between December 1, 2015 and June, 2016 the automotive sector is working to modify the design and manufacturing processes to meet the 2016 deadline of using an alternative material.

Replacement brake assemblies containing copper continue to be manufactured between January 31, 2012 and June 2016, in order to ensure that replacement parts are available to provide continued serviceability for consumers.

Additional brake assemblies containing copper may need to be made after the June 2016 date to provide service and replacement parts for automobiles manufactured prior to June, 2016.

*Example is selected for demonstrative purposes only.

If “Historic Product” is limited to products manufactured prior to the date the product is listed, then automobiles and replacement parts manufactured after January 31, 2012 but prior to June, 2016 would

not necessarily be considered “Historic Products” and could be subject to regulatory response, despite being designed prior to completion of any alternative assessment. It is unclear in the regulations how such products would be treated. The ambiguity of the proposed language could open the door to varying interpretations of how to handle these products manufactured in the interim and could create compliance difficulties for manufacturers, as well as DTSC.

As currently proposed, in the example above, replacement parts manufactured between January 31, 2012 and June 2016 and/or manufactured after June 2016 would also not be considered “Historic Products”; these products could be subject to the June 2016 requirements, despite the Department’s verbal clarification that it is not its intent to regulate such products.⁶ This narrow scope regarding replacement parts is problematic for two reasons. First, for specialized parts, companies often produce lifetime supplies of replacement parts during the first year of a vehicle model. In the case of our example, replacement parts for Model Years (MY) 2012–2016 automobiles would already be in inventory at dealers, service shops, auto repair stores, etc. They would likely remain in commerce for 10-12 years in order for consumers to repair, or have repaired, their vehicles as produced. While the definition of manufacturer in §69501.1(a)(40) exempts repair or refurbishment from the definition of manufacture, it does not exempt the products needed to perform that repair or refurbishment. Therefore, these existing inventories of replacement parts produced in the interim time between a priority listing and regulatory response date could not comply with this regulation.

A second and equally serious concern is that some volume of replacement parts manufactured after June 2016 would be needed to meet the same product specifications and requirements for pre-June 2016 vehicles; in this case, brake assemblies employing copper as a friction material. If functionally equivalent replacement parts for older vehicles are not available because they cannot be manufactured using the same materials as the original product, many automobile manufacturers may not be able to meet their warranty obligations, and consumers will not be able to get their vehicles repaired. In the extreme cases where service and repair facilities attempt to design “work arounds” to extend the lifetime of the vehicle, performance and safety may be compromised.

This current approach in the regulatory text to historic products and replacement parts falls short of the goal to create a forward-looking regulation and would divert resources from investing in greener technology for future products as manufacturers are forced to reinvest in the design and development of new replacement parts for older vehicles. To redesign or reengineer these replacement parts and perform the safety and performance testing required before they could be placed on the market would be cost and time prohibitive, and as DTSC recognized, “would not represent a high volume chemical in commerce” (ISOR, p. 29). For example, lamps employing mercury free technology are not interchangeable with mercury-based headlamps. The housings, wiring assemblies and connections to the main vehicle are not interchangeable. If replacement parts (mercury-based lamps) are not available for the lifetime of the vehicle, a broken headlamp will make the automobile inoperable. If the exemption stands as written, the availability of replacement parts is likely to be disrupted, consumers

⁶October 4, 2012 teleconference between DTSC and Global Automakers.

will not be able to repair their vehicles, which would devalue their investment in a vehicle, and repair shops and companies that manufacture and use these parts will be significantly disadvantaged by losses in revenue.

Broad exemptions for replacement parts can be found in the ELV Directive, RoHS Directive, and multiple other federal and state environmental regulations. For example, the RoHS Directive (Article 2(3)) makes it clear that the directive does not apply to spare parts for the repair of electrical and electronic equipment put on the market before July 1, 2006, in order to ensure the availability of spare parts for equipment placed on the market before the entry into force of the substance restrictions. More recently, laws in California (SB 346, "Hazardous Materials; Motor Vehicle Brake Friction Materials," 2010) and Washington (SB 6557, "Brake Friction Materials – Restrictions on Uses," 2010) regarding the copper content in brake friction materials both provided exemptions for service and replacement parts in recognition of the above noted concerns. Consequently, we believe the regulations should be revised as described below.

Recommendations:

The cleanest way to exempt replacement parts is to include a new definition for "replacement parts" that includes the language "repair as produced", as used in the ELV.

Revise **§69501.1(a)** to add a new definition (additions are shown in red and underlined text):

"Replacement Parts" means any part, component, subcomponent or product needed to repair as produced a product.

(A) Replacement parts must meet the regulatory requirements in place at the time of original production of the product.

(B) Replacement parts are exempt from coverage under these regulations if they are produced to repair a product manufactured prior to any determined regulatory response.

Corresponding language would need to be added to the Regulatory Response section, specifically exempting replacement parts from regulatory response requirements if they are produced solely for the intent of repairing a product as produced, which was manufactured prior to the designated regulatory response.

If the DTSC does not want to add a new definition for "Replacement Parts," then to ensure the clear exemption for replacement parts that is needed, additions to the current "Historic Product" definition and a new definition for "Interim Parts" would be needed, as follows:

Revise **§69501.1(a)(22)(B)2.** to read as follows:

2. "Historic product" means one of the following:

(i) A product that ceased to be manufactured prior to the date the product is listed as a priority product;

* (ii) A product manufactured in accordance with a design certified or approved by a federal regulatory agency or the Department of Defense prior to the date of the final regulatory response for the Priority Product; or,

(iii) A product that is used as replacement part or component of a product identified in (A) or (B) regardless of when it was manufactured but meeting all applicable regulatory requirements at the time of first manufacture.

Add a new definition to **§69501.1(a)(22)(B)3.** to read as follows:

3. “Interim Product” is a consumer product manufactured between the time it was identified in a proposed or final Priority Product list and the effective date for any related regulatory response, and includes spare parts or components used for repair or maintenance of such a consumer product. No regulatory response shall be imposed on any interim products.

Revise **Section 69506.1** to add new subsection **(b)**:

(b) This article does not apply to any interim products. Manufacturers may optionally apply a regulatory response to an interim product.

While this alternative definition would address the concerns that we have with the historic product definition as proposed, we strongly recommend that DTSC adopt our first recommendation and include a new definition that would specifically exempt replacement parts using the concept of “Repair as Produced.”

B. §69503.5 Alternative Analysis Threshold

§69503.5(c) *The Department shall specify an alternative analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product. In establishing an alternative analysis threshold, the Department shall, except as provided in paragraph (3), take into consideration, based on available reliable information, the factors specified in paragraph (1) if relevant, and paragraph (2):*

§69503.5(c)(2)(A) *The minimum concentration of the Chemical of Concern that can be detected with available laboratory analytical methodology. (B) The Department shall not specify an alternatives analysis threshold that is lower than the minimum detectable concentration for the Chemical of Concern.*

Over the course of the development of these regulations, DTSC has put forward a number of different approaches to establishing an exemption for chemical concentrations that fall below a certain limit or threshold. Chemicals of Concern above the stipulated threshold would trigger the requirement for an Alternatives Analyses to be completed for the Chemical of Concern in a Priority Product. The current proposal no longer specifies a default concentration-based trigger that determines whether a manufacturer can qualify for an exemption from the Alternative Analysis (AA) requirement. Instead, DTSC has proposed to specify an individual threshold for each Chemical of Concern in a Priority Product. In setting this threshold, DTSC must consider the ease or difficulty of removing the Chemical of Concern from a product if it is a “contaminant,” the detection limit for the Chemical of Concern, and public health and environmental considerations.

Based on the discussion in the ISOR, DTSC has determined that the term Alternative Analysis Threshold (AAT) will be used instead of the term “de minimis.” The AAT is a concentration below which there is an exemption from the duty to conduct an AA and above which an AA is required. This was done to clarify DTSC’s rationale for including this concept as part of the regulations and to “minimize the possibility for confusion or misunderstanding that this threshold represents an insignificant or negligible risk, too small to be of concern (ISOR, p. 105).

If the newly proposed AAT is not intended to be a threshold that would make some distinction between chemicals present in concentrations that would cause concern and negligible concentrations that would not, then it is not clear what DTSC intended the proposed exemption to accomplish and what that threshold represents. The criteria proposed to support the exemption are not based on accepted scientific standards for distinguishing between levels of concern and levels of insignificant impact. Consider the following definitions:

- **De Minimis** - “*De minimis* is a Latin expression meaning *about minimal things*. In risk assessment, it refers to a level of risk that is too small to be concerned with.” [Wikipedia] or the concentration below which concern or risk is negligible.
- **Detection Limit** - In analytical chemistry, the **detection limit, lower limit of detection, or LOD** (limit of detection), is the lowest quantity of a substance that can be distinguished from the absence of that substance (a *blank value*) within a stated confidence limit (generally 1%). [Wikipedia]

The concept of “de minimis” in environmental regulatory schemes is used to focus research, assessment and mitigation on areas, or in this case products, where chemicals are present at levels where (1) exposure is likely and (2) harm may result.

The concept of “detection limit” as presented in the current proposal refers to the lowest quantity of a substance that can be detected. With the phenomenal advances in analytical technologies, the detection limit of any given chemical is: (1) an ever decreasing number and (2) representative of miniscule presence, not exposure potential. Using the detection limit as the default threshold value,

even when combined with the qualitative criteria in §69503.5(c)(1)(A)-(D) provides no distinction between insignificant risk potential and potential risk and consequently provides no value in terms of priority setting. While we recognize that the intent of including the reference to the detection limit is to provide a “floor” below which DTSC will not go for the AAT, it is important that DTSC make clear that it is not their intent to default to the detection limit.

The reason that this issue is of such concern to Global Automakers and its member companies is two-fold. First, in those instances where a Chemical of Concern may be identified in one of our products, we will work in cooperation with DTSC to fully assess the nature of the concern and the potential for exposure and risk. Committing to such an assessment is costly, time consuming and will drain resources from our future-oriented research and development work. When DTSC identifies its priority list of chemical and product combinations we want to be sure that we are all focused on significant and relevant issues – not “minimal” risk and not “the lowest quantity that can be distinguished from the absence of that substance.” We should all be focused on those chemical and product combinations where the hazard is well characterized, the exposure potential is clearly present, and the risk is real, not perceived.

The second and equally important basis for our concern is the direct relationship between whatever threshold level established by DTSC and the automotive industry’s ability to continue to use its two main sources of product information and data – the Global Automotive Declarable Substance List (GADSL) and the International Material Data System (IMDS).

GADSL provides a definitive list of substances that are regulated by governments – both domestic and international. Its intent is to ensure cost-effective management of regulatory requirements along a complex supply chain. GADSL includes information on regulated substances relevant to parts and materials supplied throughout the automotive value chain. GADSL includes substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale. In most cases, the listings in GADSL are based on the threshold levels routinely assigned at 0.1%.

In response to GADSL, the automotive industry developed IMDS to serve as the automotive industry’s material data system. It has been adopted as the global standard for reporting material content in the automotive industry and recognizing what chemicals, when contained or released from finished materials and components for the automotive industry, are of concern to human health, environmental safety and/or recycling. IMDS is used primarily by automotive original equipment manufacturers (OEMs) to understand and manage environmentally relevant aspects of the design and development of different parts used in vehicles. In most cases, the threshold for reporting for this system is 0.1% by weight.

If a threshold level for setting priorities for alternative assessments is set below the 0.1%, a threshold that has been almost universally adopted by international regulatory bodies, in most cases the automotive sector will lose the ability to use the very set of tools which will allow it to identify what parts or components of their products contain the Priority Chemical. While DTSC has deemed the chemical lists generated at these levels to be appropriate for wholesale adoption, DTSC appears to have

determined that these same organizations are using inadequate threshold levels. The automotive sector has made significant investments in these data systems over the past 10-12 years so that the sector could be forward thinking, could make informed environmental choices and be in compliance with regulations impacting our products. If DTSC adopts a threshold level lower than the 0.1% used by these systems, our industry will likely have no readily available source of supplier information. In the short term, the impact on our industry will be significant as we struggle to access information from a wide and diverse supply chain to ascertain which of our products may contain listed chemicals. The costs in time and dollars will be massive with minimal benefit to the SCP program.

Recommendations:

Global Automakers supports the exemption originally proposed in the November, 2010 draft of the Safer Consumer Product Regulations. DTSC proposed that the threshold below which an AA would not be required would be defined as: “a concentration less than or equal to 0.1 %” (§69301.2, November 2010 Draft Regulations). This threshold level is consistent with other state, federal and international threshold levels and provides for a meaningful distinction between those chemical/product combinations that have the potential to pose a risk and those that do not. The most meaningful health and environmental benefits will be achieved by targeting exposures above a threshold of 0.1% within a product’s total weight.

We recognize that DTSC is under great pressure to expand rather than reduce the scope of these regulations. DTSC has chosen to work with a large universe of chemicals, a full spectrum of both human health and environmental effects and an extensive set of exposure pathways and scenarios. While we believe a more manageable set of chemicals and endpoints would have been preferable for the start of this program, we are focusing our comments on adopting a meaningful and science based threshold that will provide real product priority setting, regulatory relief and burden reduction. A 0.1% AAT will accomplish these objectives without narrowing the scope of DTSC’s coverage and will provide regulatory certainty for those subject to the regulations.

Based on the comments received to date by various stakeholders and DTSC’s direction in the July 2012 proposal, Global Automakers understands that a common 0.1% AAT for all chemical/product combinations is not a preferred option. Nevertheless, given DTSC’s limited resources for implementing the rules, the use of 0.1% globally, and in the case of the automotive industry, a database premised on such a level, Global Automakers believes that 0.1% remains the best approach and any deviance from this default level will result in the need for additional time to identify products under the proposed Priority Product Notification process.

C. §69501.1(a)(21) Components

§69501.1(a)(21) *“Component” means a uniquely identifiable part, piece, assembly or subassembly, system or subsystem of a consumer product that:*
(A) Is required to complete or finish an item;

- (B) Performs a distinctive and necessary function in the operation of a system; or
- (C) Is intended to be included as part of a finished item.

The proposed definition of component is overly broad for sectors engaged in manufacturing complex durable products such as automobiles. Such goods have complicated systems that are made up of multiple individual components or parts. On average, an automobile is made of approximately 30,000 individual parts – some as simple as a gasket others as complex as the electronics system. As currently written, a component could be identified as a transmission system, an automotive electrical system or an automotive interior. In looking at a transmission system for example, there are over 60 major parts.

As an example, If DTSC were to list the chemical/product combination of a specified chemical in automotive transmission systems, the automotive sector would be subject to an overly broad and potentially insurmountable challenge of assessing over 60 individual components. Even with the proposed language in §69503.4(a)(2) that limits the number of components to no more than 10 per product every three years for durable goods, the potential for a sector being required to perform extensive alternative assessments is possible, even if not likely.

Example: Components in a Transmission System

Adjustable pedal	Differential case	Pinion
Axle shaft	Pinion bearing	Planetary gear set
Bell housing	Differential clutch	Shift cable
Belt	Spider gears	Shift fork
Timing belt	Differential casing	Shift knob
Cam belt	Differential flange	Shift lever
Other belts	Differential gear	Slave cylinder
Carrier assembly	Differential seal	Speed reducer
Chain wheel and sprocket	Flywheel	Speedometer gear
Clutch assembly	Flywheel ring gear	Steering gear
Clutch cable	Gear	Torque converter
Clutch disk	Gear coupling	Transaxle housing
Clutch fan	Gear pump	Transfer case
Clutch fork	Gear ring	Transmission gear
Clutch hose	Gear stick (<i>gearstick, gear lever, selection lever, shift stick, gear shifter</i>)	Transmission pan
Clutch lever	Gearbox	Transmission seal and bonded piston
Clutch lining	Idler gear	Transmission spring
Clutch pedal	Knuckle	Transmission yolk
Clutch pressure plate	Master cylinder	Universal joint
Clutch shoe	Output shaft	
Clutch spring		
Differential		

It is important that DTSC narrow the definition of component for complex durable goods such as automobiles to ensure the AA process is manageable in size and appropriate for the time allotted to perform the AA. We recommend focusing on materials within a uniquely identifiable part or piece. In

this example then, it would be appropriate to list the clutch pedal as the product, not the entire transmission system. By adopting this more focused definition, the AA process becomes more workable for both DTSC and industry, because the target product is better defined. A narrower definition also increases the likelihood that alternative chemicals could be incorporated into the product in the short term, rather than over a longer phase out period.

It is important to recognize that for durable goods there will likely be multiple alternatives for the selected component that will need to be evaluated during both Phase I and Phase II of the AA process. The AA process will be resource intensive, and the more alternatives that need to be included in the AA, the more time and effort the AA will take. For example, the recently released draft of the U.S. EPA's Design for the Environment (DfE) Alternative Analysis report for decaBDE identified 22 alternative chemicals that were considered to be "viable" alternatives for decaBDE in the automotive sector. The EPA DfE AA process for phthalates has identified over 60 alternatives. If DTSC were to list an automotive component containing a Chemical of Concern as a Priority Product, automobile manufacturers would be faced with looking at multiple alternatives in Phase I and some subset of that in Phase II. We believe that any automotive component that is listed will have multiple alternatives to be assessed. In order to ensure that the AAs can be conducted in a timely manner and that the manufacturer has adequate resource to conduct the AAs for each Priority Product, the number of Priority Products (components) that can be selected should be limited. For this reason, we request that DTSC limit the number of components for any given product to no more than three (3) every three years.

During our October 4, 2012 teleconference, DTSC added clarity to its intent to narrowly define "component" in such a way as to precisely identify the product of concern. DTSC confirmed that they recognize that the more precise they can be in identifying a unique component the more effective they will be in addressing areas of real concern. DTSC was interested in why this was such an important issue for Global Automakers and specifically asked "what do we manufacture that might get captured" in the regulations? DTSC characterized automobile producers as "assemblers" not manufacturers and questioned why auto "assemblers" would have a duty to comply in lieu of the component manufacturer. This raises two critical areas that need clarification.

First, is it DTSC's intent to exempt the automotive manufacturing or "assembling" sector, a request we have made through multiple venues? If it is DTSC's intent that the automotive sector does not have a duty to comply as a "manufacturer," it is imperative to add clarifying language to the regulations so that our sector, as well as any others that may fall in the same category, are clear as to their regulatory status. Second, if that is not DTSC's intent, then we are confused by the current definition of "manufacture" which means "to make, produce or assemble." Based on this definition we see no distinction between producer, manufacturer or assembler and question why DTSC believed that the automotive sector would have little if any need to comply with requirements associated with an automotive component that they acquired from a supplier. Even if the regulations focus on a component made by a supplier, the automaker must still notify the supplier of the SCP requirements, provide design specifications based on the SCP regulatory response, and

ensure that the end product complies with any regulatory requirements before incorporating the component into the final product. If it is DTSC's intent, as conveyed by their questions and comments to Global Automakers, that product assemblers (including all automobile "manufacturers" and OEM suppliers thereto) would not have a duty to comply, then DTSC should clearly provide a definition that expressly exempts us and remove "assemble" from the definition of manufacturer.

Recommendations:

Global Automakers requests that DTSC clarify the status of automobile producers and their duty to comply versus automotive component suppliers and their duty to comply.

Global Automakers also recommends that DTSC add language to §69501.1(a)(21) that distinguishes between complex durable goods and less complex products and includes the concept of accessibility. We also recommend modifying § 69503.4(a)(2) to limit the number of components that can be listed in any given three year cycle. The importance of this language is to provide certainty that DTSC will select the most simplistic component within a complex durable good. Suggested language would read as follows:

§69501.1(a)(21) "Component" means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product, or for a highly durable product, a uniquely identifiable material within a single identifiable part or piece not comprised of subparts, that:

- (A) Is required to complete or finish an item
- (B) Performs a distinctive or necessary function in the operation of a product or part of a product
- (C) Is intended to be included as a part of a finished item.

§ 69503.4(a)(2) For each listed highly durable product, the Department shall specify no more than three (3) components per product every three (3) years.

D. Lead Time Requirements for Implementing Changes in the Automotive Sector

The current SCP proposal provides for compliance and implementation schedules that are identical for every industrial sector. Given the wide range of complexity and differences between sectors, we recommend that DTSC either adopt a more tailored approach that recognizes the different challenges that will confront complex product manufacturers with multi-tiered supply chains such as automobile manufacturers or extend the timeframes for all covered sectors.

To put these comments in the proper context, it is important to understand the lengthy and complex product development cycles in the automobile industry. Because automobiles are highly complex and

innovative products, their development from the concept to the engineering phase takes several years. Engine development, powertrain components, fuel systems, and materials and manufacturing processes can take significantly longer. Requirements for safety and durability testing also add additional time to the process. To modify or reengineer automobiles to meet new regulatory requirements, the auto industry needs sufficient lead time to design, test and manufacture any new parts or components. The European Union (EU), which has had considerable experience with the implementation of the REACH regulations, submitted comments to DTSC that clearly question the ability of manufacturers or DTSC to meet the timeframes proposed given the complexity of the AA requirements (EU Comments to DTSC, September 11, 2012). We share this concern. As we noted earlier, the more specific the component that is identified, the more likely it is for the responsible party to complete the AA process, but even this detail will not correct for the necessary information exchanged between a multi-tiered, international supply chain nor the potential number of alternatives that will need to be assessed.

1. Priority Product Notifications

§69503.4(g) *Each responsible entity for a product listed on the Priority Products list shall provide to the Department one of the following notifications within sixty (60) days after the product is listed as a Priority Product, or sixty (60) days after the product is first placed into the stream of commerce in California, whichever is later:*

- (1) Priority Product Notification, as specified in §69503.7*
- (2) Alternative Analysis Threshold Exemption Notification, as specified in §69503.6*
- (3) Priority Product removal notification and, if applicable, A Priority Product Replacement Notification, as specified in §69501.2(b); or*
- (4) Chemical of Concern removal notification, as specified in §69505.1(g)*

Depending on the AAT adopted by DTSC in the final regulation, sixty days may be inadequate for the automotive sector to identify the presence of a Chemical of Concern in a Priority Product and file the appropriate response from §69503.4(g)(1)-(4). As discussed in more detail in our comments related to the AAT, if the automotive sector cannot use the databases and tools (IMDS and GADSL) that it has developed to ensure compliance throughout the supply chain, it will require significantly longer than 60 days to work throughout the supply chain to request information on the listed chemical and product combination. For example, if a specified chemical and product combination, like copper in brake pads, were identified at a threshold level below 0.1%, an automobile manufacturer would need to individually contact each Tier 1 supplier that could potentially use the chemical through a questionnaire or directly call them. Each of these Tier 1 suppliers would have to reach down through a supply chain that could be as many as 3 or 4 tiers where suppliers could be in many different countries. In this particular example, it could take up to six months to gather reliable information depending on the complexity of the component and the depth of the supplier chain. If DTSC determines to use an AAT below 0.1%, we

request that the time frame for these responses be expanded to “up to six months” if data is not readily available.⁷

2. Preliminary AA

§69505.1(c)(3)(A) *Except as provided in subsection (d)(1), the responsible entity shall submit the Preliminary AA Report no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department’s website, unless the Department specifies a different due date for the product in the Priority Products List under §69503.4(a)(2)(C).*

We request that DTSC extend the timeframe for submission of the preliminary AA Report. The due date for the report is linked to the listing date on the Priority Products list as well as being dependent on the Priority Product notification. As discussed above, we believe the sixty day Priority Product notification timeframe may be too short in some cases and should be extended, or be more flexible. In addition to the additional time needed for the notification process, there will be many circumstances where the Preliminary AA Report will take longer than ten months to prepare (12 months minus the 60 days for notification). The Preliminary AA Report requires identification of functional requirements, alternatives and an initial screen of the alternatives identified. Depending on the complexity of the chemical/product combination and the number of the alternatives to be considered, it could easily take much longer to complete a Preliminary AA Report that would meet DTSC’s requirements and needs.

For example, the U.S. EPA’s Design for the Environment (DfE) program develops AAs through a partnership process. In addition to a full time DfE staff, each chemical partnership has 40-60 actively engaged stakeholders that work with the DfE staff to identify alternatives, assess functionality, collect hazard and exposure data, and work collaboratively to develop the final AA. The DfE’s AA for hexabromocyclododecane (HBCD) that covered two (2) alternatives began in April 2011 and will not be completed until the spring of 2013. The AA for decaBDE that identified 32 alternatives, 22 of which were considered viable alternatives for the automotive sector, began in October 2010 and will not be complete until December 2013. An AA for BPA in Thermal Paper, a very limited scope for the assessment, identified 19 alternatives. The AA work began in July 2010 and will not be complete until December 2013. These AA’s are complex assessments and depending on the number of alternatives that will need to be assessed, U.S. EPA’s experience has demonstrated that one year is insufficient time to complete an assessment that will be deemed “compliant” by DTSC.

We recognize that DTSC has included language that provides them with the authority to establish a “different due date,” but that language is open ended and provides no criteria to allow the regulated

⁷ Alternatively, DTSC could maintain the current 60 days for notification but allow for an extension up to 120 days based on the individual parties needs. Global Automakers, however, does not recommend the extension process because the request for extension would involve both company and DTSC resources that are better applied to implementation.

community to anticipate what timeframes DTSC would believe are reasonable for complex durable products such as automobiles.

We request that DTSC either (1) extend the timeframe for the Preliminary AA Report to 18 months from the submission of the Priority Product notification, and/or (2) provide criteria that would allow the regulated community to identify an appropriate timeframe when they submit the Priority Product Notification.

3. Final AA

§69505.1(c)(3)(B) *Except as provided in subsection (d)(1), the responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, under section 69505.5(k)(1), and the Department approves, under §69505.6(a)(3), a longer period of time.*

We believe that triggering the start date of the Final AA Report from the date DTSC issues a notice of compliance for the Preliminary AA Report is a workable approach. We also recognize that DTSC has provided for a one time extension request and appreciate that degree of flexibility in the timing. However, Phase Two of the AA process is focused on in-depth alternatives analyses and development of regulatory approaches. Depending on the number of alternatives to be assessed, twelve months may be insufficient to complete this process in any meaningful way and in such a manner that will be acceptable to DTSC (see U.S. EPA DfE examples cited earlier). This phase of the AA process is a de facto risk assessment for all alternatives. To be done well, these assessments will require extensive data collection, hazard and exposure assessment, functionality determinations, safety standard compliance determinations, economic impacts assessment and in some cases consumer acceptance testing.

Global Automakers recommends that DTSC reconsider the timing requirements for the Final AA Reports. The amount of time provided for submission of the Final AA report should be proportional to the number of alternatives to be assessed and the complexity of the product being studied. If federal or state safety standards are involved, the time required to test for efficacy in meeting those standards needs to be factored into the due date. If data needs to be developed, that development time should also be a consideration. Twelve months may be workable for a simple product with one or two alternatives. Twelve months would be inadequate for a complex product with 10-12 potential alternatives and the need for safety determinations.

In addition to the procedural concerns about the timing requirements proposed in these regulations we ask that DTSC be mindful of the time required to implement changes to an automobiles design and manufacturing process. §69505.6 addresses Department Review and Determinations for AA reports and §69506.12 addresses Regulatory Response Report and Notifications. We request that DTSC include language in these sections that recognizes the many compliance schedules will be measured in years, not months.

We also want to note general concern about the process that DTSC will use to determine that a Final AA has met all requirements. Based on industry trade secret concerns, it is likely that many AAs will be conducted independently, resulting in numerous findings or regulatory responses based on any one company's determination of "safer." For instance, the draft DecaBDE Alternative Assessment Report released by the EPA DfE Program looked at 22 "viable" alternatives for the automotive sector, but in all of the draft findings, no single alternative provides an overall benefit for the identified hazards. Instead, there are tradeoffs between the health and environmental benefits, and this information suggests that there may not be a "safer" alternative. Any company using this information to inform future product decisions could select any one of the alternatives depending on what attribute they decide is most important. It is not clear how DTSC will assess decisions or how clarity can be given to a company looking for assistance in selecting a "safer" alternative. We have no recommendation for this concern, but instead, we believe that DTSC must keep these sorts of challenges in mind as the program moves forward and additional regulatory clarity based on experiences can be provided through guidance or regulatory amendments.

E. §69503.3(b) Other Regulatory Programs

Global Automakers is concerned about the language in §69503.3(b), specifically the proposal that:

If a product is regulated or is subject to pending regulation by another entity, with respect to one or more adverse impacts or exposure pathways, the Department shall adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment with respect to the adverse impacts and/or exposure pathways associated with the product.

This language does not provide industry with any regulatory certainty, unlike the guiding language from the statute, SB 509, which clearly directs the department to avoid duplication or conflicting with other regulations: "The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article (SB 509, Chaptered 560, September 29, 2008). To meet both the spirit and the letter of that direction, we believe that DTSC should, at a minimum, exempt chemical/product categories that are already regulated or pending regulation by Federal and state authorities for the same or essentially equivalent health or environmental concerns or targeting the same chemical of concern. Federal regulation would cover the product nationally, thereby resulting in duplication, and existing or pending regulations at the state level are often de facto national regulations for our sector.

DTSC's current proposal to "adjust the prioritization of the product" does not meet either the standard in SB 509 or the direction in AB 1879 to reference and use "to the maximum extent feasible" available information from other regulatory bodies. If DTSC's overall intent as articulated in its ISOR is to develop

a “preemptive strategy that reduces the use of toxic substances in the design of products” then focusing any resources on already regulated and controlled products is duplicative and will create regulatory uncertainty for any industrial sector already regulated (ISOR, p. 5). In many cases, any replacement or redesign of a product or component in our sector will require extensive safety and performance testing that is regulated by other state and federal agencies. Duplication in this area would undermine the continued investment in green technology causing a “wait and see” approach that is counter-productive to our industry’s goals.

For example, in DTSC’s ISOR in support of the proposed SCP regulations, DTSC states that the rules could be used to require an Alternatives Analysis of automotive catalytic converters in an effort to reduce greenhouse gas (GHG) emissions (ISOR, p. 22). Under the proposed SCP regulations, DTSC would claim authority to select products that contain, emit or are manufactured using any of the more than 1000 initially listed “Chemicals of Concern,” including certain GHGs that are emitted from automobiles or used in vehicle air conditioning systems. The manufacturers, importers and retailers of these products could be called on to perform in-depth “Alternatives Analyses” – costly studies that could take months to perform – in order to identify substitute materials or alternative manufacturing processes. Using these studies, the DTSC could implement regulatory responses that include product redesign, changes in raw materials, engineering controls or product use restrictions.

DTSC officials have indicated that they believe the rules provide the Department with the authority to address GHG emissions from motor vehicles. We are concerned that DTSC’s overly broad interpretation of their regulatory reach has the strong potential for the DTSC to issue regulations that interfere with existing light duty vehicle emissions regulations already in place in California, and perhaps for the DTSC to issue its own suite of vehicle GHG regulations.

The automotive industry has worked closely with the U.S. Environmental Protection Agency (EPA), the California Air Resources Board (ARB) and the National Highway Traffic Safety Administration (NHTSA) to develop a program that would achieve the goals of this Administration’s “One National Program” for GHG emission reductions by creating regulatory consistency and certainty through a single compliance pathway. “One National Program” was implemented to address the fact that these three regulatory agencies were each seeking to exert independent regulatory authority over motor vehicle fuel economy and GHG emissions, creating an unworkable patchwork of regulations. Having finally resolved that problem through implementation of the harmonized One National Program, it would not only be disruptive if a fourth agency (DTSC) seeks to exert new authority over the same kinds of issues but duplicative, conflicting and inappropriate.

We have similar concerns with DTSC’s exercise of regulatory control over products that have been adequately regulated by other state agencies and whose benefits will be seen in California. Examples here include copper in brake pads, Bisphenol A in children’s products, flame retardants in textiles and multiple other regulated chemical and product combinations.

Global Automakers requests that DTSC modify the language in **§69503.3(b)** as follows (additions shown in red and underlined; deletions shown in strikethrough text):

§69503.3(b) If a product is regulated or is subject to pending regulation by another entity, with respect to one or more adverse impacts or exposure pathways, for the same or essentially equivalent health or environmental concerns, the Department shall ~~adjust~~ ~~the prioritization of~~ exempt the product based on the determination that ~~whether~~ listing the product as a Priority Product would not meaningfully enhance protection of public health and/or the environment with respect to the adverse impacts and/or exposure pathways associated with the product.

(1) Other regulatory requirements that do not directly impact the health and environmental concerns but require safety, durability or other performance based standards will be taken into consideration as part of the product prioritization factors in § 69503.2 and product's functionality in § 69505.3.

Global Automakers also requests that DTSC add the following language in **§ 69501.1(a)(22)(B)2.** for consistency with the language in SB 509:

§ 69501.1(a)(22)(B)2. “Consumer Product” or “Product” does not include a product, or a component of a product that is regulated or pending regulation by another federal or state entity, with respect to one or more adverse impacts or exposure pathways, for the same or essentially equivalent health or environmental concerns for the listed Chemical of Concern.

F. §69506.8 End of Life Management Requirements

§69506.8 outlines the End of Life (EOL) management requirements for Priority Products. As proposed, the manufacturer of the final product bears a disproportionate share of the responsibility for developing EOL programs, state and local infrastructure programs and all related costs. Product Stewardship should assign responsibility all along the supply chain including all intermediate suppliers as well as the consumer. Products are designed to meet the needs of consumer demands. If consumers are not assigned some responsibility in DTSC's regulatory approach then all the upfront work to encourage sustainable approaches will be negated. If the final manufacturer is responsible for all aspects of EOL management, there is no incentive for all players along the supply chain to invest in green design and development.

The automotive sector has already demonstrated a commitment to EOL management of wastes and believes the financial guarantee provisions are inappropriate. According to the Argonne National Laboratory and the Department of Energy, “In the United States today, more than 95% of vehicles are recycled in a process that is market driven rather than government mandated. Of end-of-life vehicles (ELV's) more than 75% of material, by weight, is recycled” (CRADA Team for End of Life Recycling).

Global Automakers appreciates that DTSC has proposed an exemption provision regarding the development of an EOL management program (§69306.8(d)). However, it is not clear what DTSC means by “demonstrating to the Department’s satisfaction” that an EOL program cannot be feasibly implemented for the product or what criteria the Department will use to assess whether any additional program is needed at all. Given the critical importance of the EOL requirements, more precision is needed in the regulation to clarify those circumstances when an exemption would be applicable.

Global Automakers recommends that DTSC rework §69506.8 to include language that places responsibility on all responsible parties, including state and local government, for creating the needed public infrastructure, and consumers for following safe and sustainable disposal practices. We recommend that DTSC remove the financial guarantee language for sectors, such as the automotive sector, that have demonstrated effective programs in this area. Additionally, DTSC should consider ways to promote and incentivize more effective collection, segregation and recycling of consumer wastes.

G. §69501.1 Unintentionally Added Chemicals and Chemicals with no Exposure Pathway

The current SCP proposal does not include a definition for “unintentionally” added chemicals. The November 2010 draft of the regulations defined unintentionally added as: “‘Unintentionally-added chemical or chemical ingredient’ means a chemical or chemical ingredient that is present in a consumer product but is not an intentionally-added chemical or chemical ingredient” and provided for an exemption from the AA process for these chemicals (Draft SCP Regulations, November 2010, p. 18). The purpose for this exemption was to further refine the priority setting process to focus on Chemicals of Concern and Priority Products. Chemicals that are unintentionally present are usually considered impurities and ranked low for exposure potential. Because DTSC has not included a supplier notification process in the proposed regulations, manufacturers have no way of knowing what impurities may be present in materials they further process or use. If a chemical is unintentionally present, it is likely that (1) the manufacturer is unaware of its presence; (2) it is likely present in very low concentrations and presents minimal exposure potential; and (3) DTSC will not have any exposure data by which to prioritize the chemical/product category. By utilizing this common sense exemption DTSC will allow both itself and the regulated community to address issues of concern.

Global Automakers requests that DTSC adopt the definition originally proposed in the November 2010 draft and amend § 69501.1(c) to specifically exempt unintentionally added chemicals, naturally occurring contaminants in raw materials, and contaminants in recycled materials. If DTSC has concerns that there may be some exposures of concern associated with unintentionally-added chemicals then we recommend a phased in approach where unintentionally added chemicals are exempted for the first five (5) years of the program and then DTSC evaluates the need to include them after that time.

For the same reasons articulated for unintentionally-added chemicals, Global Automakers recommends including an exemption for chemicals that have no exposure pathway. If a chemical is present in a

product in such a way that there is no potential for exposure, there would be no sound basis for including that chemical/product combination on a priority list. We recognize that DTSC will “consider” exposure pathways as it sets priorities among chemicals and products, however the term “consider” provides no regulatory certainty for the regulated community. If the concern for chemicals with no exposure pathway has to do with potential end of life exposures, then we request that DTSC identify those chemicals and limit the AA to end of life practices.

Global Automakers urges DTSC to reconsider the removal of these two common sense exemptions from the draft regulations. Both of these earlier provisions provided a filtering system [a funneling system] to assist DTSC in further refining the list of chemical/product combinations that would form the basis of the priority listing.

H. Compliance and Enforcement

1. Compliance

Global Automakers requests that DTSC provide more specific criteria to be used in making determinations about the adequacy of submitted AA and the submitter’s compliance with the regulations. In multiple instances these proposed regulations provide DTSC with open ended authority to determine that more data or information is needed – the concern is that there is no identified end to the process.

For example, § 69506.2(a) states:

The Department may at any time require a responsible entity to provide, within a timeframe specified by the Department, any information supplementary to the Final AA Report that the Department determines is necessary to select and ensure implementation of one or more regulatory responses that may be imposed under this article.

There are no criteria as to what is “necessary” and what limits will guide DTSC’s actions in this area. Similarly, § 69506.2(b) states:

The Department may at any time require a responsible entity to obtain or develop, within a time frame specified by the Department, information to fill one or more of the information gaps identified in the AA Report...

This vague and overly broad authority would allow to DTSC to require anything from a minor piece of data to a full blown testing scheme.

We strongly recommend that DTSC learn from the experiences with the Maine regulations and provide clear guidance and criteria as to what constitutes compliance.

2. Enforcement

Global Automakers is also concerned about the ability of DTSC to enforce the requirements of these proposed regulations and to ensure a level playing field for those companies who make the substantial investments need to fully comply with the final regulatory requirements. In their comments to DTSC, the EU identified a number of enforcement weaknesses. These comments are particularly compelling in that they come from an organization that has considerable experience implementing the REACH legislation, a regulation with many similarities to the proposed SCP regulations. Specifically, the EU has pointed out severe deficiencies in the enforceability of the initial notification process and all work flowing from that notification process. (EU Comments to DTSC, September 1, 2012, p.2) We question the legality of a state regulatory program that cannot be effectively enforced and request that DTSC reassess the enforceability of this effort.

For the most part, the automotive sector produces “50-state cars”, automobiles that meet the strictest standards in place at the federal and state level. The products that we manufacture will be manufactured to meet California’s requirements, as well as all other domestic requirements and in certain cases international requirements. When California’s SCP regulations are in place, Global Automakers members will work diligently to comply with whatever requirements may be mandated and will put in place whatever programs are necessary to ensure compliance. This compliance action will include looking across the supply chain and putting systems in place to identify chemical/product combinations that are identified by DTSC as Priority Products. For our sector, we will need to monitor our supply base both domestically and internationally. We may need to put testing programs in place; at a minimum we will need to create complex information and data systems.

How will DTSC ensure compliance with these regulations? If responsible companies invest time and resources in developing the infrastructure that will allow them to be confident they are in compliance, how will DTSC ensure a level playing field across the entire regulated community? Those who invest in the tools necessary to comply will be placed at a significant economic disadvantage if DTSC cannot safeguard that all companies have made the same investments.

Our concerns in the area of enforcement are best characterized by a series of questions that have not been answered.

- Who will enforce these regulations?
- Does DTSC or the State of California have the resources to put an effective enforcement program in place?
- Does DTSC have the technology and the facilities to support an enforcement program?
- How will DTSC monitor imports?

- How will DTSC manage “consumer imports” or products that are brought into California by consumers

Global Automakers requests that DTSC develop a section on Enforcement for these regulations to provide both the regulated community and the general public with a clear sense of expectations for enforcement of the program.

I. Compliance with CEQA

The California Environmental Quality Act (CEQA) requires that DTSC prepare an in-depth Environmental Impact Report (EIR) before adopting any proposed regulations. An exemption to this requirement may be granted only if the requesting agency demonstrates that there is no potential for significant adverse effect on public health or the environment. In posting a draft Notice of Exemption on its website, DTSC has indicated its intent to assert that there will be no significant adverse effect on public health or the environment. Given the very nature of these regulations and the extent to which they will fundamentally impact California’s environmental and public health, it is clear that there will be significant impacts. As we have indicated in our comments, we believe that these regulations have the potential to drive premature and potentially harmful chemical substitution choices. We have raised concerns that consumer safety could be jeopardized by limitations on products and components that ensure both performance and safety standards are met.

We believe this rulemaking does not qualify for a statutory exemption under CEQA and support the more extensive comments in this area submitted by the Alliance of Automobile Manufacturers.

J. APA Requirements

California’s Administrative Procedures Act (APA) requires that DTSC assess the “potential for adverse economic impact on California business enterprises and individuals” prior to promulgation of any regulations. In February 2012, the California Office of Administrative Law (OAL) updated the procedural requirements for all rulemakings to include new provisions primarily affecting policy development and economic impact analysis during the pre-notice stage of rulemaking from SB 617 (Stats. 2011, Ch. 496):

- 1) *An agency must consider reasonable alternatives including those which are proposed as less burdensome and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the authorizing statute or other law being implemented or made specific by the proposed regulation.*
- 2) *An agency must prepare an economic impact analysis that includes the benefits of the regulation to the health and welfare of California residents, worker safety, and the state’s environment to inform the agencies and the public of the economic consequences of regulatory choices.*

- 3) *The analyses conducted on proposed regulations are intended to provide agencies and the public with tools to determine whether the regulatory proposal is an efficient and effective means of implementing the policy decisions enacted in statute or by other provisions of law in the least burdensome, cost effective manner.*
- 4) *The baseline for regulatory analysis shall be the most cost-effective set of regulatory measures that are equally effective in achieving the purpose of the regulation in a manner that ensures full compliance with the authorizing statute or other law being implemented or made specific by the proposed regulation. (Cal OAL Feb, 2012).*

DTSC has not complied with these requirements and has instead developed an incomplete economic analysis that does not address even the most basic requirements of the APA. The analysis that DTSC has completed fails to address fundamental economic considerations such as job growth or loss; business impacts; consumer impacts, and local community impacts. While there are numerous sources of information on programs similar to the one DTSC is proposing (REACH, TSCA, State Programs) , DTSC has chosen not to use historic data and has instead claimed that there is no data that would provide even a “best estimate” as to what the cost to California would be.

The recently released report, “The Consumer Impact of California’s Green Chemistry Initiative,” (October 3, 2012) from the California Foundation for Commerce and Education underscores the flimsy nature of DTSC’s assessment and highlights the significant potential for adverse economic impact on business, jobs, and California’s economy.

Global Automakers is also concerned about the lack of transparency in how DTSC is addressing the comments that come into the Department as a result of the Public Comment periods and/or the Public Meetings. §11346.9 of California’s APA states:

Every agency subject to this chapter shall do the following:

(a) Prepare and submit to the office with the adopted regulation a final statement of reasons that shall include all of the following:

(3) A summary of each objection or recommendation made regarding the specific adoption, amendment, or repeal proposed, together with an explanation of how the proposed action has been changed to accommodate each objection or recommendation, or the reasons for making no change.

Each consecutive draft of the proposed regulations has changed significantly and there is no indication of how or why the changes were made. Because DTSC does post all the comments on their website, it is possible to review all the comments that have been submitted. What is not obvious, or transparent, is how DTSC makes its decisions on what comments it will “accept” and what comments it will “reject.” So for example, there have been various exemptions included in early drafts and then removed in later drafts, like the exemption for intentionally-added chemicals (see Section G of this comment).. What is missing is any discussion or comment response document from DTSC that explains why changes were

made and why others were not. Global Automakers requests that DTSC provide this type of decision-making background to the public for review prior to finalization of this rulemaking.

K. Conclusion

Global Automakers continues to believe that this type of regulatory scheme, as designed, is not appropriate for application for complex durable goods. Durable goods are heavily regulated at the international, federal and state level, and in achieving compliance with all applicable regulations, as well as with internal safety and performance standards, we continue to provide safe and effective products for all consumers.

Global Automakers and its members are committed to working with DTSC to make this regulatory scheme one that is effective, meaningful, practical and legally defensible. Much work has gone into developing the overarching framework and the underlying principles throughout the pre-proposal process. Our concerns now with the proposed regulations and ISOR are focused predominantly on the technicalities of implementation; the what, the how and the when.

As we have indicated in our previous comments and in recent meetings with DTSC, the clear and comprehensive exemption of automotive replacement parts remains our top priority. It is clear from the ISOR that DTSC does not intend to extend the scope of coverage of the SCP regulations to replacement parts, and based on our October 4, 2012 meeting with DTSC, we believe that we are in agreement that replacement parts manufactured prior to the implementation date of any regulatory response should be exempt from these regulations. This issue can be easily and effectively addressed, without impacting the intended scope of the regulations, by including a clear definition for replacement parts and the accompanying exemption language. While we appreciate that the language in the ISOR is a good faith effort of demonstrating intent, it is the regulatory text that will govern compliance determinations.

We also believe that we share a common goal as relates to the definition of components and the need to be as specific and as targeted as possible. We urge DTSC to consider the language that we have proposed and to limit the number of components that any one sector would need to address in a three year period to no more than three.

The issue of timing remains a major concern. From the requirement to submit a Priority Product Notification (PPN) to the final implementation of any selected regulatory response, there is inherent uncertainty in the process. The more significant the product selected, the more alternatives that need to be assessed, and the more tiers within the supply chain will all contribute to the Phase I and Phase II AA processes being more complex and lengthy. It is clear that there is not a one size fits all timeframe for the AA process or for the PPN. While the ability to request extensions can be a helpful and necessary flexibility, it creates an unfair burden on manufacturers of complex durable goods to have to automatically default to requests for extension and a difficult strain on resources for both the

manufacturers and the Department to have to submit. We strongly recommend that DTSC revise the proposal to allow more time for complex products, such as automobiles, or provide for a case by case determination of timeframes for all consumer products.

We remain concerned about the potential for regulatory overlap and duplication. DTSC's retreat from their previous exemption for products regulated by other statutes raises significant questions as to what DTSC intends in terms of revisiting other state or federal regulatory requirements. We believe that the statutory language is clear that these situations, where the same health and environmental endpoints are targeted, that the product would be exempt from the SCP requirements.

We have also raised concerns about the AAT level, EOL management requirements, exemptions for unintentionally-added chemicals, compliance and enforcement, and compliance with CEQA and APA requirements. Each of these areas represents one more opportunity to adjust this proposal in such a way as to make it more effective and efficient.



1111 19th Street NW > Suite 402 > Washington, DC 20036
t 202.872.5955 f 202.872.9354 www.aham.org

October 11, 2012

Krycia Von Burg
Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Re: Proposed Regulations, R-2011-02, Safer Consumer Products

Submitted via E-Mail

Ms. Von Burg:

On behalf of the Association of Home Appliance Manufacturers (AHAM), I would like to provide our comments on the California Department of Toxic Substances Control's (DTSC) Proposed Regulation R-2011-02 Safer Consumer Products.

AHAM represents manufacturers of major, portable and floor care home appliances, and suppliers to the industry. AHAM's membership includes over 150 companies throughout the world. In the U.S., AHAM members employ tens of thousands of people and produce more than 95% of the household appliances shipped for sale. The factory shipment value of these products is more than \$30 billion annually. The home appliance industry, through its products and innovation, is essential to U.S. consumer lifestyle, health, safety and convenience. Through its technology, employees and productivity, the industry contributes significantly to U.S. jobs and economic security. Home appliances are also a success story in terms of energy efficiency and environmental protection. New appliances often represent the most effective choice a consumer can make to reduce home energy use and costs.

AHAM supports DTSC's intent to limit potential exposures or the level of potential adverse impacts posed by toxic chemicals in consumer products. However, the scope of the regulation is unnecessarily broad and AHAM believes that because home appliances are well-regulated in this area already, they should not be the focus of this regulation, if not entirely excluded from the prioritization process. DTSC's treatment of home appliances in such a manner would be consistent with the Department's objectives for the following reasons.

I. Home appliances are well-regulated by other entities

Sections 69503.2 and 69503.3 of the proposed regulation both state that "Other Regulatory Programs" are among the factors DTSC must consider in its prioritization process. With respect to home appliances, this factor should be dispositive in granting AHAM products a very low

priority, or excluding them entirely. Home appliances are already well-regulated at the federal level through a number of agencies.

Under the Consumer Product Safety Commission alone, AHAM's members must conform to regulations under several pieces of legislation, including the Consumer Product Safety Act, The Consumer Product Safety Improvement Act, and the Refrigerator Safety Act. The Toxic Substances Control Act, as administered by the U.S. Environmental Protection Agency (EPA), also requires mandatory reporting and safety requirements relating to chemicals that pose potential risks. This is in addition to mandatory greenhouse gas reporting rules. In addition, the U.S. Department of Energy (DOE) regulates energy conservation of appliances under the Energy Policy and Conservation Act of 1975 (EPCA), as amended by the Energy Policy Act of 2005 and the Energy Independence and Security Act of 2007. The Federal Trade Commission also mandates energy labeling for many of these same products under Energy Policy and Conservation Act. In addition, though not a mandatory regulatory program, the success of the ENERGY STAR program, administered by DOE and EPA, has made it mandatory in the market place.

Furthermore, the appliance industry is already taking significant voluntary steps to achieve the goals of DTSC's proposed regulations. AHAM is publishing a series of sustainability standards for major, portable and floor care appliances that address materials of concern. The Safer Consumer Products regulations would therefore not have any significant impact in protecting human or environmental health, but would instead simply serve as an unnecessary burden on an already stressed industry.

II. Prioritization Factors

A. Intended Product Uses

Section 69503.2(a)(1)(B)(1) of the proposed regulation states that “[b]ased on reliable information, the Department shall also give special consideration to the ability of the Chemical(s) of Concern in the product to contribute to or cause widespread adverse public health and/or environmental impacts.” One of the factors DTSC is to consider is “intended product use(s), and types and age groups of targeted customer base(s).”

While AHAM acknowledges that its members' products are used by a broad cross-section of consumers, the products do not contribute to or cause widespread adverse public health and/or environmental impacts. If AHAM products are not going to be excluded from the prioritization process, then this provision of the regulation seems to indicate that they warrant special consideration and lower prioritization than products that are directly aimed at these individuals.

B. Containment of Chemicals of Concern

Section 69503.2(a)(1)(B)4(d) of the proposed regulation states that another factor is “[p]ublic and/or aquatic, avian, or terrestrial animal or plant organism exposures to the Chemical(s) of Concern in the product during the product's life cycle, considering... [c]ontainment of the Chemical(s) of Concern within the product.”

As stated before, any direct exposure to chemicals is already regulated by other entities, therefore, with respect to appliances, this provision goes toward any other Chemical(s) of Concern that may be present. If a Chemical of Concern were to be present in home appliance products, it is likely to be part of a component contained within the appliance. Such components present much less of a risk to the consumer than those that involve direct contact with the user. Given these facts, that such a chemical would largely be contained within the appliance furthers the reasons that home appliances are low enough priority under the proposed regulations that they should be excluded from its scope.

C. Disposal of home appliances at end-of-life

Section 69503.2(a)(1)(B)5 of the proposed regulation states that DTSC must consider “[p]roduct uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts.”

Implied in this provision is that DTSC should also consider product end-of-life scenarios that minimize adverse consumer impacts. Especially with regard to major appliances, the home appliance industry and its products already benefit from a decades-old established market-based system in which these units are collected and recycled at over 90 percent. The fact that the home appliance industry is far ahead of most others in developing a system to deal with end-of-life issues further illustrates that the industry should not be included during DTSC’s prioritization process.

III. Conclusion

AHAM emphasizes that DTSC’s proposed regulations have too broad a scope, and that the scope should be altered to exclude home appliances. These products are well-regulated and DTSC’s action will not decrease any risk these products might pose, but would instead impose unnecessary burdens on their manufacturers during an already challenging economic time. If DTSC chooses not to exclude these products, the provisions specified above show that home appliances should not be considered a priority product under reasonable circumstances.

Submitted respectfully,



Kevin Messner
Vice President, Policy & Government Relations



William H. Devine
Vice President
Legislative Affairs

AT&T California
1215 K Street, Suite 1800
Sacramento, CA 95814

T: 916.341.3400
F: 916.447.6680
bdevine@att.com

October 11, 2012

Ms. Krysia Von Burg
Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

On behalf of AT&T, I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Products Regulation ("regulation") of July 2012.

AT&T is a technology and communications company and one of the largest, union employers in California. We have a strong commitment to sustainability and the environment and were recently added to Corporate Responsibility Magazine's 12th Annual *100 Best Corporate Citizens List*. One example of our commitment to sustainability is our 5-star eco-rating system that was developed to provide eco-conscious customers with a way of evaluating the mobile devices they are considering.

The eco-rating system assesses 15 specific criteria drawn from five general categories of sustainability attributes – attributes include the usage of environmentally preferable materials, minimizations of hazardous substances, energy efficiency, responsible end-of-life treatment and environmentally responsible manufacturing. These criteria are then calculated into AT&T's 5-star system, with five stars being the highest. We also have [eco-space](#), a website with additional information for the public about our eco-rating system.

Because of our commitment to sustainability, we appreciate the considerable effort DTSC has invested in its effort to develop an efficient and effective regulatory system. We recognize the proposed regulations are the product of a lot of meetings and input over several years. However, we agree with Green Chemistry Alliance (GCA) Coalition's concerns that DTSC is proposing a far-reaching regulatory scheme that is so amorphous that businesses will not have the certainty they need to ensure compliance or to conduct their normal course of business. We also echo the concerns of the many business groups that have cited the lack of a thorough economic impact analysis of these regulations..

In addition to these general concerns, there are a few additional areas of particular interest to a technology and communications company like AT&T:

1. Our initial concern is with the unprecedented scope and applicability of the proposed regulations: "*all consumer products placed into the stream of commerce in California.*" (§ 69501 (b)(1)). With very limited exceptions, the definition of "consumer product" in these regulations includes virtually every tangible product made available to consumers in California, whether that product is an everyday household product offered to individual consumers at the neighborhood grocery or hardware store, or sophisticated capital equipment or technology-related products purchased by a commercial consumer for use in the operation of its business or to support its commercial customers; all are included within the scope of these regulations. By definition, millions of California consumers will be affected by these regulations, as well as hundreds of thousands of businesses, both large and small, in and outside of California, the United States, and beyond. In effect, these regulations give DTSC the power to act as a *de facto* gatekeeper and to regulate all products sold in the State of California; a power not likely envisioned by the authors of the enabling legislation (AB1879/SB509, 2008).

Furthermore, while these regulations and the enabling legislation have at their core the objective of protecting the health and welfare of California consumers and providing a framework for the development of "safer consumer products," they are also likely to have the unintended consequence of severely impacting the ability of California businesses, like AT&T, to meet the needs of their customers as more and more products they rely on to conduct their businesses become unavailable in the marketplace as manufactures and retailers simply choose to no longer offer those products in California due to the staggering compliance obligations required under these regulations.

For the foregoing reasons, AT&T respectfully requests that DTSC reassess the scope of its regulation and narrow the scope to only those products typically offered to *individual* consumers (not businesses) and to only those products that present the greatest exposure-risk to specific chemicals of concern.

2. To the extent DTSC retains its expansive definition of "consumer product" under these regulations, we are concerned that the proposed exclusion of "historic product[s]," as defined, is too narrow and should not be limited to products that have already "ceased to be manufactured prior to the date the product is listed as a Priority Product," but should also include all products that remain in production and continue to be marketed until such time as an appropriate regulatory response has been determined. We note that this broader definition was previously included in the Revised Informal Draft Regulations (May 2012). As DTSC notes in its Initial Statement of Reasons (July 2012), this regulation is intended to be "forward looking" and to "accelerate the quest for safer consumer products" and so its regulations should be focused on identifying the requirements necessary to manufacture safer consumer products in the future and not create unnecessary compliance obligations for products that have already been manufactured and introduced into the California marketplace.

We also note that the proposed definition of "historic product" fails to include the necessary repair or replacement parts to maintain such products, also originally included in the Revised Informal Draft. The continued manufacture and availability of repair and replacement parts without being subject to these regulations is critical to maintaining the cost-effective support and operation of these products for our customers. As DTSC also noted in the Initial Statement of Reasons, the definition of "manufacture" is intended to also exclude "replacement parts" as may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference replacement parts.

We recommend that the definition of "historic product" be restored to the version that was included in the Revised Informal Draft Regulations (May 2012) and that the definition of "manufacture" also be modified to exclude repair and replacement parts.

3. Additionally, as a California retailer of communications-related products, and not a manufacturer, we are very concerned with the obligations that DTSC requires of "retailers" who may sell products that contain a chemical of concern. While the regulations state that a manufacturer has the "principal duty" to comply (or an Importer, if any), the regulations nonetheless require the retailer, as a "responsible entity" to bear the full weight of compliance with these regulations (including Alternatives Analysis) if the manufacturer and importer fail to do so for any reason. We note that the regulations do provide a "retailer option" which allows a retailer to avoid its default compliance obligations, but only by ceasing to order (and sell) any priority product that contains a chemical of concern. Once again, this approach goes far beyond the intent of the enabling legislation and effectively penalizes retailers and consumers from the benefits of being able to offer and utilize lawfully produced products in this state.

We would ask that DTSC limit the core compliance obligations under these regulations to the actual manufacturers who control the materials and components utilized in their products and to limit any obligations on the part of retailers to appropriate and narrowly tailored regulatory responses as may be required on a case by case basis.

Ms. Krysia Von Burg

October 11, 2012

Page 3

4. Creating a list of 1,200 chemicals of concern can cause undue alarm for consumers and will inevitably lead to businesses having to respond to those fears. We support the idea of limiting the term "chemical of concern" to those chemicals that have been determined to present a serious risk of harm and exposure to consumers. The term "chemicals of interest" should be used for the rest of the chemicals that DTSC has listed.
5. Any "alternatives analysis" of identified products must be performed by individuals competent not only in chemistry but in the disciplines of product development. Also, the performance and efficacy of products for their intended purpose in the marketplace must not be lost. Technology and communications products of the type utilized by AT&T in its networks and made available to our customers have very unique and specific requirements in order to function optimally. We believe that maintaining this functionality at the same level should be a key component of any alternatives analysis.

We appreciate your consideration of our concerns. For further information or questions, please contact Jay Maille at 925-823-7430.

Sincerely,



William H. Devine

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

GCREgs@DTSC

From: faith attaguile <faith_attaguile@hotmail.com>
Sent: Monday, October 01, 2012 9:51 AM
To: GCREgs@DTSC
Subject: Toxic Substances Regulations

Categories: Comment

Sir or Madam:

Your job is to protect public health first (that means your children and your families, too), not corporate profits.

Toxic chemicals in the products we use must be regulated and removed. Period.

Thank you.
Faith Attaguile

October 10, 2012

Debbie Raphael, Director
California Department of Toxic Substances Control
1001 "I" Street
Sacramento, CA 95812

Re: Comments of the Automotive Aftermarket Industry Association and California
Automotive Wholesalers Association on Proposed Safer Consumer Products
Regulations

Dear Ms. Raphael:

The Automotive Aftermarket Industry Association (AAIA), on behalf of our member organization, the California Automotive Wholesalers Association (CAWA), and our full membership base thank you for this opportunity to provide comments regarding the proposed Safer Consumer Products regulation (22 CCR, div 4.5, ch. 55).

AAIA is recognized as the pre-eminent trade association and voice for the \$297.5 billion motor vehicle aftermarket, which employs four million people and contributes more than two percent of the U.S. gross domestic product. AAIA's more than 23,000 member and affiliates manufacture, distribute and sell motor vehicle parts, accessories, service, tools, equipment, materials and supplies across the country. Through its membership, AAIA represents more than 100,000 repair shops, parts stores and distribution outlets nationally.

CAWA is a non-profit trade association representing 450 automotive aftermarket parts manufacturers, jobbers, warehouse distributors and retailers in California, Nevada, and Arizona. The Association was formed in 1955 and serves as the voice of the aftermarket parts industry in the West. CAWA prides itself on quality customer service to its members and the industry.

Statement of Concern:

AAIA members appreciate the goal of the California green chemistry initiative; however the current proposed Safer Consumer Products regulation will impose severe adverse effects on the aftermarket industry in California. The automotive aftermarket employs nearly 350,000 individuals and accounts for more than \$32 billion in sales in California annually. Given the significant economic contribution to the State, AAIA believes the Department of Toxic Substance Control (DTSC) should perform a robust economic analysis of the proposed Safer Consumer Product regulations prior to implementation.

In addition to a comprehensive economic analysis of the impact of these rules on California businesses, AAIA also submits specific comments on the proposed language. These comments are intended to reduce unnecessary burdens that will be placed on many of the state's

small businesses should the currently drafted rule be adopted while still ensuring car owners have access to repairs necessary for the safe and efficient operation of their vehicles.

Currently, the proposed language contains several definitions and requirements that are far too broad. These areas within the regulations contribute to the expansive scope of the proposal creating the potential inability for responsible entities to reasonably respond to the concerns of the DTSC.

Furthermore, deadlines offered by the regulation do not take into account the complex and highly-regulated nature of the aftermarket. The aftermarket industry must already be responsive to existing timeframes for responsible product development, safety testing, national regulatory compliance, state regulatory compliance, international and domestic trade responsibilities, and other environment and safety-related circumstances. The proposed regulation currently imposes timelines for responsible entities that could put them in violation of already existing requirements that hold precedence over the authority of the Safer Consumer Products regulation.

The comments provided by the Complex Durable Goods Coalition with respect to the Safer Consumer Products regulation address in-depth many of the concerns shared by the AAIA. This organization agrees with those recommendations and would like to associate the AAIA with those statements, and all included documents to those comments. In order for DTSC to properly understand and respond to the concerns of the AAIA with regard to the current proposed regulation, some recommendations for remedies relevant to the most critical issues facing the aftermarket are detailed below.

Recommendations:

1) Modification to the definition of “Manufacture”

The definition provided in §69501.1 (40) for “manufacture” should not include the three listed actions of (A), (B), and (C) under any circumstances. The majority of automotive aftermarket entities involved in the business of repairing vehicles or returning them to working order under the regulations of the California Department of Motor Vehicles do not possess the capabilities to “manufacture” consumer products in the generally understood sense of the term. These businesses rely upon a network of organizations within the aftermarket supply chain to provide them with the necessary tools, equipment, parts and consumer products to operate their businesses. The manufacturing of items required to undertake automotive repair have occurred long before and by several other entities prior to reaching the repair-focused business.

Identifying activities such as “repair,” “refurbish,” “installation of standardized components,” and “making non-material alterations,” could hold repair-focused businesses accountable for the content of Chemicals of Concern in products after having no control over the initial methods of production that dictated the product make-up. This would be similar to holding the homeowner who prefers do-it-yourself repairs accountable for the chemical content of the paint they purchased from their local hardware store.

Furthermore, automotive repair-focused entities are typically small businesses that simply cannot shoulder the cost burden of the alternatives analysis and regulatory process outlined in the current proposed regulation. The threat of such expense could be crippling to the future planning

of automotive repair businesses in California and ultimately weaken the availability of convenient, reasonably-priced vehicle servicing locations in the State.

Proposed language:

§69501.1 (a) (40) “Manufacture” means to make, produce, or assemble. “Manufacture” does not include any of the following actions, ~~unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:~~

- (A) Repair or refurbishment of an existing consumer product;
- (B) Installation of standardized components to an existing consumer product; or
- (C) Making non-material alterations to an existing consumer product.

2) Revised definition of “historic product” and exemption for service parts of “historic products”

The AAIA agrees that “historic products” should be exempted from the definition of “consumer product” or “product,” as found in §69501.1 (22)(B)(1) & (2), AAIA urges that the exemption be extended to service parts for historic products. Parts to repair historic products were developed based on certain parameters generated around those historic items. The proposed regulation defines a “historic product” as no longer being in production. Therefore, significant concern exists around the ability to reengineer service products that continue to perform properly as a part of an original product that is no longer in production. Changing the composition of these service parts could significantly alter the ability of historic products to operate.

Proposed language:

§69501.1 (22)(B)(1) “Consumer product” or “Product” does not mean any historic product or service part intended to repair, refurbish or maintain a historic product.

§69501.1 (22)(B)(2) “Historic product” means ~~a product that ceased to be manufactured prior to the date the product is listed as a Priority Product~~ one of the following:

- (i) A product that ceased to be manufactured prior to the date the product is listed as a Priority Product;
- (ii) A product manufactured in accordance with national or international standards requiring certification of compliance with those standards prior to the date the product is listed as a Priority Product; or
- (iii) A product that is used as a spare part or component for repair or maintenance of a product identified in (A) or (B) regardless of when it was manufactured.

3) Narrow the definition of “component”

The definition of "component" in §69501.1 (21) is far too broad and should be more narrowly focused to address the specific material within a consumer product that causes the measurable and significant threat to public health. The inclusion of entire assemblies, subassemblies, systems, or subsystems creates an unnecessarily burdensome scope for responsible entities to address when working to respond to the requests of the proposed regulation.

The definition of "component" should be narrowed to only one piece or part of an overall product. More narrowly focusing the definition can streamline the process to achieve the desired outcome of the Safer Consumer Products regulation. This would allow both identifiers of priority products and the entities responsible for addressing the Chemicals of Concern within those products to more efficiently and effectively attack the public health threat at a minimum burden to businesses.

Proposed language:

§69501.1 (21) "Component" means a uniquely identifiable part, piece, or a material within a part, piece of a consumer product or for a highly durable product, a uniquely identifiable material within a single identifiable part or piece not comprised of subparts, that:

- (A) Is required to complete or finish an item
- (B) Performs a distinctive or necessary function in the operation of a product or part of a product
- (C) Is intended to be included as a part of a finished item

In conclusion, the automotive aftermarket is extremely concerned with the direct impact that the proposed Safer Consumer Products regulation will have on the ability to continue providing vehicle solutions to the state of California. We urge that a full economic analysis of these rules be completed and further urge that the DTSC consider adoption of the proposed changes we have included in these comments in order to mitigate the significant potential burden that these rules will place on our industry.

Thank you for the opportunity to provide our comments on the proposed Safer Consumer Products regulation and we look forward to working with you on coming to an agreement that is both beneficial to public health and safety as well as reasonable for businesses.

Sincerely,



Aaron Lowe
Vice President, Government Affairs
AAIA

From: Michael E Heltzer <michael.heltzer@basf.com>
Sent: Thursday, October 11, 2012 11:56 AM
To: GCREgs@DTSC
Subject: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

BASF Corporation is submitting comments regarding the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Alternatives Regulation of July 2012, which has been issued pursuant to the 2008 enactment of Assembly Bill 1879. Stats. 2008, c. 559 (AB 1879). BASF supports the intent of the proposed regulation, which Director Raphael has referred to as a "systematic approach to reducing toxic chemicals in consumer products," and we appreciate the fact that this version has opted to focus the program initially by only identifying up to five priority products. However, we still cannot endorse the current draft and believe the proposed regulation will be more effective if the regulated community and consumers can operate under a greater degree of certainty.

BASF Corporation is the North American subsidiary of BASF SE – *The Chemical Company*. We combine economic success, social responsibility and environmental protection. Through science and innovation we enable our customers in almost all industries to meet the current and future needs of society. Our products and system solutions contribute to conserving resources, ensuring healthy food and nutrition and helping to improve quality of life. We have summed up this contribution in our corporate purpose: *We create chemistry for a sustainable future*. BASF has five facilities in the state of California (Rancho Cucamonga, Orange, Newark, Dinuba, and Fremont), and we are a member of groups active in discussions related to the green chemistry issue, including the American Chemistry Council, American Cleaning Institute and Green Chemistry Alliance.

Among the more critical areas where the proposal lacks clarity is the manner in which DTSC will distinguish between or prioritize the respective hazard traits or environmental or toxicological endpoints that caused a chemical to be placed on the initial list of 1200-plus "chemicals of concern." §69502.2(a). DTSC should utilize a subsequent prioritization to identify a discrete subset of the highest priority chemicals in that group of 1200-plus, which should rightly be identified as "chemicals of concern." In short, 1200-plus actionable chemicals is far too unwieldy, and the goal of DTSC should be a manageable process focusing on chemicals which exhibit the greatest hazards, *i.e.*, substances known to cause cancer or developmental or reproductive harm and substances known to be persistent, bioaccumulative and toxic in the environment as designated by the U.S. Environmental Protection Agency and others.

Other examples where clarity in the proposed rule would be appropriate include, but are not limited to the following:

- The process of using "reliable information" to assess whether a chemical should be added to the "chemicals of concern" list. §69502.2(b)(3). We suggest this should be clarified by incorporating a specific and scientific weight-of-the-evidence assessment. In doing so, DTSC will correctly avoid allowing a single study, regardless of its quality, to be the determining factor in a chemical's placement on the list.
-
- DTSC's response to public comments. The proposed regulation leaves the door open to the possibility that DTSC may not respond to all public comments. §69502.3(d). Given the scope and the likely impact of the safer alternative program, a response by DTSC to all comments it receives seems appropriate.
-
- The assessment and and prioritization of products. As drafted, the regulation identifies a vague, subjective process by which DTSC will establish a list of "priority products." We recommend DTSC create a clear, step-by-step and more objective analysis that utilizes credible, scientifically valid measurements in order to determine which products will be regulated.

Related to the issue of clarity, BASF also believes that the scope of the current proposal, which would establish an all-encompassing program covering virtually all commercially available products and their packaging, *e.g.*, bulk chemicals,

goes beyond the intent of the Legislature when it adopted AB 1879. We suggest that the Legislature intended DTSC to take a more modest approach and focus attention on minimizing the potential for exposure to hazardous chemicals of concern in more everyday consumer products and to encourage innovation in these products that safeguards human health. In our opinion, the approach in the draft regulation for such broad product coverage will create an unworkable framework that will increase uncertainty in the business community.

BASF appreciates DTSC's consideration of our concerns, and remains supportive of the intent of the proposed regulation and underlying statute. Please contact me if you have any questions.

Sincerely,

Michael E. Heltzer

BASF Corporation, Government Affairs Department

Phone: 973-245-6035 Mobile: 973-876-2492 Fax: 973-245-6706 E-Mail: michael.heltzer@basf.com

Postal Address: 100 Park Avenue, Florham Park, NJ 07932



December 30, 2011

VIA ELECTRONIC FILING

Department of Toxic Substances Control
Attn: Heather Jones – Safer Consumer Products Regulations, MS-22A
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: California DTSC Safer Consumer Products Regulations Draft

Dear Ms. Jones:

The Battery Council International (BCI) is pleased to submit these comments on the California Department of Toxic Substances Control's (DTSC) informal draft regulations for Safer Consumer Products. Health and Safety Code sections 25252 and 25253 require DTSC to adopt these regulations to: 1) establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized; and 2) develop criteria by which chemicals and their alternatives may be evaluated and reduce exposure to these chemicals and the hazards posed by them.

BCI is a non-profit trade association whose members are engaged in the manufacture, distribution and reclamation of lead batteries. BCI members account for over 98% of the U.S. lead battery production and over 80% of its recycling capacity (*i.e.*, secondary lead smelting). Our industry promotes lead-acid battery recycling by collecting and recycling lead batteries, encouraging the enactment of mandatory lead battery recycling laws, and supporting ongoing consumer and industry environment, health and safety education efforts. The vast majority of used lead-acid batteries are collected initially for recycling from consumers, either at retail outlets that sell new batteries, or at retail facilities where new batteries are both sold and installed. These batteries are picked up from retailers by battery distributors, battery manufacturers or secondary lead smelters and delivered to recycling facilities. The U.S. recycling rate for lead from lead-acid batteries is very close to 100%.¹

For the reasons presented below, BCI recommends that the DTSC exempt lead-acid batteries from the requirements of the Safer Products regulations. Lead-acid batteries and

¹ Smith, Bucklin and Associates, Inc., *BCI National Recycling Rate Study* (August 2009). The recycling rate for lead from lead-acid batteries across the years 2004 – 2008 was 96.0%. The plastic battery casings also are recovered and processed into raw material for new products.

their production and recycling are time-tested and already highly successful and regulated. There also are no viable substitutes that meet the critical performance and cost efficiency (technical and cost feasibility) requirements demanded by the marketplace and the rule's Alternatives Assessment provisions.

Comments

1. Lead-Acid Batteries Should Be Exempted From the Rule as They Are Already Highly Regulated

DTSC recognizes in the draft proposal that an exemption should be provided for products that are already regulated by one or more federal, California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that

“address[es] the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and provide[s] a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product.”

Lead-acid batteries are such a product. As more fully explained in the following subsections, they are already subject to a state disposal prohibition and mandatory recycling (end-of-life product management), they must display consumer warnings pursuant to both Proposition 65 and U.S. Consumer Product Safety Commission (CPSC) requirements, and lead-acid battery manufacturing and recycling are both strictly regulated under the Clean Air Act, the Clean Water Act and California's hazardous waste regulations. Cal/OSHA's general industry lead standard also serves to control worker exposure to lead during battery manufacturing and recycling. Indeed, Cal/OSHA has this year initiated a rulemaking process that may make its lead standard more stringent.

These characteristics are precisely those which, under the proposed regulation, would support DTSC excluding lead-acid batteries. But this could only be done after an independent Alternatives Assessment was completed. There is no reason for resources to be wasted in that effort. Lead-acid batteries should be excluded from the start.

a. End of Life Product Management for Lead-Acid Batteries

With BCI's strong support, thirty-nine states, including California, have enacted laws that assure “cradle to grave” stewardship of lead batteries. These laws prohibit municipal solid waste landfill or incinerator disposal of used batteries and require battery retailers to accept used batteries from customers and advertise their collection

obligations. Battery manufacturers and distributors, in turn, must accept the used batteries from retailers and transport them to recycling facilities at their own expense.²

The existing reverse distribution system – whereby the same network that distributes new batteries also safely collects and returns used batteries for recycling – satisfies these legal requirements and assures that batteries are recycled at very high levels, regardless of the price of lead. Lead battery manufacturers also developed an industry battery label to further assure lead-acid battery recycling. It consists of the words “LEAD-RETURN-RECYCLE” surrounding the three-chasing-arrows recycling symbol.

Furthermore, California’s end-of-life product management law specifically prohibits municipal solid waste landfill or incinerator disposal of used lead batteries, and requires battery retailers to accept used lead batteries offered by customers. Battery manufacturers and distributors, in turn, must accept the used batteries from retailers and ensure for recycling. Battery manufacturers must notify retailers and distributors of these requirements. Cal. Health & Safety Code § 25215.

As noted above, the U.S. recycling rate for lead from lead-acid batteries is very close to 100% – a rate that is unsurpassed by any other battery chemistry or consumer product. All of the plastic from lead-acid batteries is also recycled. The sulfuric acid electrolyte from used batteries is either recycled or neutralized. Indeed, lead-acid battery stewardship practices set the standard for other products.

b. Consumer Warnings on Lead-Acid Batteries

BCI has provided battery use and safety labeling recommendations to its members since 1989, and these are used virtually universally. They are included in BCI’s *Recommended Practices for Warning Messages, General Labeling & Marking and Shipping & Packaging* (last updated August 2009) and is the industry standard. These labels initially were designed to comply with very detailed and stringent CPSC regulations, and since have been expanded to reflect California “Proposition 65” requirements. The recommended labels are easily visible to consumers and store clerks and convey necessary information about potential hazards and safety precautions applicable to lead-acid batteries.

For example, consistent with CPSC requirements, lead-acid batteries for consumer use (*e.g.*, batteries for cars, boats, lawnmowers and power sport vehicles such as motorcycles, jet skis and snowmobiles) must be labeled with safety warnings indicating the presence of sulfuric acid, that they pose a DANGER and that acid is a POISON. Special handling and first aid instructions also are included, as well as the phrase “KEEP OUT OF THE REACH OF CHILDREN.”³ These warning statements are

² An additional five states have more narrow laws that strictly prohibit municipal solid waste disposal.

³ 16 C.F.R §§ 1500.121 and 1500.3.

located prominently on labels and appear in conspicuous and legible type in contrast by typography, layout or color with other printed material on the label. A sample label with CPSC required language is shown as Attachment 1. A nearly identical label is used on industrial lead-acid batteries to comply with U.S. Occupational Safety and Health (OSHA) requirements.

Similarly, lead-acid batteries for the U.S. market are labeled with the California Proposition 65 warning statement that indicates the presence and hazards of lead and “other chemicals known to the State of California to cause cancer” (referring to sulfuric acid mist). That statement reads as follows:

WARNING: Battery posts, terminals, and related accessories contain lead and lead compounds, chemicals known to the State of California to cause cancer and reproductive harm. Batteries also contain other chemicals known to the State of California to cause cancer. Wash hands after handling.

c. Other Regulatory Controls on Lead-Acid Batteries

The lead-acid battery manufacturing and recycling industries are strictly regulated by federal and state air, water and hazardous waste rules and regulations. Worker safety is further protected by the federal and State general industry lead standard and applicable hazard communication standards.

California implements and enforces Clean Air Act requirements that carefully limit stack emissions and the ambient air levels of lead for both battery manufacturers and battery recyclers. These requirements include the National Emissions Standards for Hazardous Air Pollutants and the National Ambient Air Quality Standard (NAAQS) for lead. The NESHAP regulations for both industries were recently updated (2007 for manufacturers and 2011 for recyclers) and the lead NAAQS was revised downward from $1.5 \mu\text{g}/\text{m}^3$ to $0.15 \mu\text{g}/\text{m}^3$ in 2008. A review of the 2008 NAAQS standard is also underway.

Water effluent limits applicable to battery manufacturers tightly control waterway and sewer water releases of lead, copper, iron, oil and grease, total suspended solids (TSS) and pH levels. Battery recyclers must meet stringent effluent limits for antimony, arsenic, lead, zinc, ammonia, TSS and pH (sulfuric acid from used batteries is separated for recycling or neutralized). Storm water releases at these facilities are also tightly controlled.

Lead-acid battery manufacturers and recyclers are also stringently regulated by the full panoply of California’s hazardous waste rules for all hazardous wastes that they generate through processes at their plants. This includes containment, storage time, recordkeeping, annual reporting, manifesting, hazardous waste hauler requirements and land disposal restrictions, among other obligations.

Generators, transporters and storage facilities handling used lead-acid batteries before recycling are covered by streamlined hazardous waste requirements that include manifesting, recordkeeping and, except generators, annual reporting obligations. 22 Cal. Code Regs. §§ 66266.80-81. In addition, any damaged batteries must be stored and transported in a non-reactive, structurally secure, closed container capable of preventing the release of acid and lead, and packed in the transport vehicle in a manner that prevents the container from tipping, spilling or breaking. Section 66266.81(b)(1).⁴ The handling of large quantities of lead-acid batteries, long-term storage of such batteries and electrolyte removal (any quantity) also trigger the full panoply of hazardous waste regulations in California described above. This covers storage of more than one ton of batteries for more than 180 days, or, one ton or less of batteries for more than one year. This latter requirement serves to minimize or even eliminate long-term storage of used batteries by generators, transporters and storage facilities.

As noted above, Cal/OSHA's general industry lead standard serves to control worker exposure to lead during battery manufacturing and recycling. Cal. Code Regs. tit. 8 § 5198. It sets personal hygiene and facility housekeeping standards that are critical to keeping blood lead levels down, as well as similarly critical limits on the allowable level of lead in the air and in workers' blood. Also, as noted above, Cal/OSHA has this year initiated a rulemaking process to make its lead standard more stringent.

2. There are No Viable Substitutes for Lead-Acid Batteries that Meet Performance and Cost Efficiency Requirements

The Safer Consumer Products proposal includes in its Alternatives Assessment provisions a requirement that viable substitutes meet specific technological and economic feasibility standards.

a. Lead-Acid Battery Performance

There are no viable substitutes to the lead-acid battery that meet the critical performance and cost efficiency requirements demanded by the marketplace or the proposed Safer Consumer Products rule's Alternatives Assessment. Because of its unsurpassed recycling rate and regulatory controls, lead-acid batteries also are a superior product if California is looking to protect the environment and ensure human health and safety.

While batteries store electricity using a variety of different chemistries, there are no "environmentally safer" alternatives to lead-acid batteries in the uses to which they currently are put that California could identify through an Alternatives Assessment. Only one other battery chemistry, nickel-cadmium, has the capability to function as a reliable starter battery (automotive, aviation, marine and lawn and garden), especially in the colder temperatures

⁴ http://www.dtsc.ca.gov/LawsRegsPolicies/Title22/upload/OEARA_REG_Title22_Ch16_Art7.pdf

that are typical to the U.S., including parts of California. However, nickel-cadmium has toxicity concerns equivalent to lead-acid batteries, is cost prohibitive for consumer applications, and has no established recycling system. Lithium-ion chemistry batteries face significant technical limitations preventing widespread use as starter batteries. For example, the only lithium-ion vehicle starter battery currently on the market is offered as an optional spare part for certain luxury sports cars, but can only be used in weather conditions above freezing (32° F). Moreover, hybrid electric vehicles that utilize non-lead technologies for the motive power battery use a separate lead-acid battery as the starter battery.

Lead-acid batteries also safely serve other diverse non-consumer applications such as medical, nuclear, motive power (*e.g.*, forklifts), standby, uninterruptible power supplies (UPS), energy storage (*e.g.*, wind, solar), load leveling (power company applications), security, emergency lighting and certain electric and hybrid electric vehicles. They operate safely and reliably at widely ranging ambient temperatures and in every geographical location, from hot desert to cold arctic environments.

New sealed (valve regulated) lead-acid battery designs have made the use of the lead-acid technology even safer in many applications. With these non-spillable batteries, the chances of acid leaking from the battery are minimal. Also, in the event of a car accident, no acid will spill out even if the battery is cracked or punctured.

The lead-acid battery is abuse tolerant, versatile and a safe and reliable battery technology.

b. Lead-Acid Battery Cost Efficiency

Lead-acid batteries are also the most affordable option when it comes to rechargeable battery technologies. Regardless of the type of application, lead-based technology delivers the lowest cost of energy and power output per kilowatt hour. No other starter battery technology is as affordable, for example. While more heavily focused in the non-consumer market, newly developed carbon-based advanced lead-acid batteries also are the most affordable battery in their class. These batteries can be used for energy storage, extended float/cycle service, UPS and hybrid electric vehicles. Advanced lead-acid batteries are 1/3rd to 1/4th the cost of competing advanced battery technologies.

An established infrastructure of manufacturing and recycling ensures that lead is one of the most stable and cost effective energy storage technologies. The recycling that is hallmark to lead-acid batteries is more energy-efficient than mining and smelting new lead or other metals for other battery chemistries. The lead from a dead battery can be refined into new alloy over and over again indefinitely. Its sustainability is unmatched and serves as a buffer to raw material price fluctuations that could compromise the practicality of commercial use. Also, the supply of lead is not dependent on one dominating international source, unlike material used in some other forms of energy power storage. The vast domestic collection and recycling infrastructure, plus the contributions from many

developed countries with safe lead-acid battery recycling facilities, also make lead one of the most reliable and environmentally sound raw materials for battery production.

* * * *

As stated at the beginning of these comments, BCI is recommending that the DTSC exempt lead-acid batteries from the requirements of the Safer Products regulations for all of the reasons described above. Lead-acid batteries and their production and recycling are time-tested and already highly successful and regulated. There also are no viable starter battery substitutes that meet the critical performance and cost efficiency requirements demanded by the marketplace, and the more expensive substitute that does exist has toxicity concerns equivalent to lead-acid batteries.

BCI appreciates the opportunity to provide these comments. If you have questions about this submittal, please contact David Weinberg, BCI's general counsel, at 202-719-7102 or dweinberg@wileyrein.com.

Respectfully submitted,

Tim J. Lafond

Timothy J. Lafond, P.E.
BCI Environmental Committee Chairman



October 10, 2012

Debbie Raphael, Director
Department of Toxic Substances Control (DTSC)
P.O. Box 806
Sacramento, CA 95812-0806

Submitted electronically to gcregs@dtsc.ca.gov

Green Chemistry Proposed Safer Consumer Products Regulations

Dear Director Raphael:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Proposed Safer Consumer Products Regulations (proposed regulations). We also wish to commend you and the DTSC staff for their systematic, science-based efforts to develop a robust process to improve product safety.

BACWA's members include fifty-five publicly-owned wastewater treatment facilities and collection system agencies serving 6.5 million San Francisco Bay Area residents. Wastewater agencies must meet increasingly strict regulatory standards to protect our water resources for a broad array of beneficial uses. We take our responsibilities for safeguarding receiving waters seriously and are very concerned about discharges of certain chemicals into wastewater systems. The growing tide of unregulated chemicals compromise effluent quality, biosolids management options and compliance with National Pollution Discharge Elimination System (NPDES) permit requirements.

Support for Proposed Regulations

BACWA generally supports the concept of green chemistry and these proposed regulations, which have a solid scientific foundation and practical framework. We believe that in time, these regulations will help reduce harmful chemicals in consumer products and thereby assist wastewater treatment agencies in protecting receiving waters.

In particular, we appreciate DTSC's efforts regarding the following elements in the proposed regulations:

- Inclusion of adverse impacts to wastewater treatment processes, water quality and aquatic life.
- Incorporation of degradates and reaction products as part of the definition of "Adverse waste and end-of-life impacts" (p. 6, line 20).
- Development of robust regulations for training and certification of Certified Alternatives Assessors as well as accreditation bodies. We understand that DTSC has limited funding and

resources to conduct Alternatives Assessments (AAs) and must rely on outside entities to assess alternatives and ensure that Certified Alternatives Assessors are qualified to conduct AAs.

While BACWA supports the proposed regulations, we also have some concerns and suggestions regarding specific sections, detailed below.

Incorporate Water Boards' Highest Priority Water Pollutants – 303(d) List

BACWA is pleased that the Proposed Regulations define “adverse water quality impacts” to include introduction or increases in pollutants that impair water bodies listed under section 303(d) of the federal Clean Water Act (p. 7, line 6). However, in the section “Chemicals of Concern Identification,” only pollutants listed under section 303(c) of the Clean Water Act are included (p. 22, line 35). A different list, developed by the Water Boards every few years under Section 303(d) of the Clean Water Act, lays out the state’s priority water pollution problems. This is the list of California’s most important water pollution problems. The 303(d) list meets all of DTSC’s stated criteria for inclusion among the lists of chemicals of concern. We hope that exclusion of 303(d) pollutants is an inadvertent omission, and request that DTSC include 303(d) pollutants in Chemicals of Concern Identification.

While there is significant overlap between pollutants in section 303(c) and pollutants that have resulted in 303(d) impairments, there are some important differences in how these lists are developed. Water bodies may be deemed impaired under section 303(d) for any pollutant, not just those listed under 303(c). The section 303(c) pollutant list does not change frequently and does not necessarily reflect pollutants affecting California waters, such as iron, manganese and molybdenum that have collectively impaired forty-five water body segments in California.¹ Including both 303(c) pollutants and the 303(d) pollutants in the “Chemicals of Concern Identification” will ensure that the highest priority water pollution problems in the state are addressed.

Incorporate High Priority Environmental Pollutants in Initial Priority Products List

BACWA understands that the proposed regulations must prioritize the vast number of consumer products; however, we are concerned that only products with human health concerns will be included in the initial Priority Products List. As currently proposed, the regulations do not allow DTSC to prioritize products containing chemicals that do not impact human health. There are products, like copper-containing vehicle brake pads, that do not directly adversely impact human health, but have dramatic impacts for the environment. We urge DTSC to consider incorporating into §69503.3 the 303(c) and 303(d) pollutants. Possible language may be added as follows to p. 29, line 12:

- 12 (3) The chemical is identified as a priority toxic pollutant for California under section 303(c) of the federal Clean Water Act or is a pollutant that has impaired one or more water bodies in California under Section 303(d) of the federal Clean Water Act.

¹ See State Water Resources Control Board 2010 303(d) list, available at http://maps.waterboards.ca.gov/webmap/303d/files/2010_USEPA_approv_303d_List_Final_122311.xls

Increase Transparency

Alternatives Assessments. While we understand that DTSC wants to expedite the Alternatives Assessment process (AA), BACWA believes the proposed regulations should include a formal comment period on preliminary AAs and any revisions to work plans. We believe a formal comment period provides greater transparency, ensures higher quality AAs, and leads to better results since many engaged stakeholders, such as BACWA and our members, can lend special expertise and provide insights that may be overlooked by both certified assessors and DTSC staff. In addition, a formal comment period will provide necessary transparency given that Certified Alternatives Assessors may be employees of the same companies required to conduct an AA.

Invite Public Comment on Product Stewardship Plans. BACWA believes that proposed Product Stewardship Plans for end-of-life management of products should be posted to the DTSC website and DTSC should invite public comment prior to approval of the plans.

Publish All Comments & Correspondence on Website. We also urge DTSC to incorporate language into §69501.5 that requires all notices, public comments, and correspondence with stakeholders to be published on the DTSC website.

Safer Products Sooner

While BACWA is encouraged by the promise of safer consumer products, we are concerned there is too much flexibility to extend the process. BACWA members have noted with some alarm the increased number of household products that contain toxic chemicals, heavy metals and nanomaterial, which may be washed down drains and impair wastewater processes and/or water quality. If the time frames are lengthy and allow too much flexibility, environmental impacts from products will not be quickly addressed. We urge DTSC to revise the proposed regulations so that time frames throughout the process are specific and as short as possible, while still allowing for reasonable public comment periods.

Consider Costs Incurred by Other Types of Entities

Municipalities, non-profit and for-profit contractors such as garbage companies may be heavily impacted by chemicals in consumer products. For example, if a chemical enters a municipal wastewater treatment plant in sufficient quantities, it is possible it could harm the crucial microorganisms used to treat wastewater, causing “process interference,” or a plant “upset” where wastewater is no longer able to be treated properly before discharge. Process interference and upsets can result in costly NPDES permit violations. In addition, when surface water bodies become impaired by pollutants, wastewater agencies may be subject to additional requirements. The cost to wastewater facilities and other dischargers to comply with new requirements can be millions of dollars which will be a cost to the public served by the treatment plant.

To address this, BACWA encourages DTSC to make two changes:

- (1) add language to the Regulatory Response Selection Principles in §69506 (p.52, lines 17-26) so that costs and other burdens (§69506 (a) (4)) incurred by other government

agencies, non-profit organizations, and certain other private businesses that manage wastes are considered when selecting a regulatory response.

- (2) add language to provide explicit direction for DTSC to consider these costs as one of the product prioritization factors (§69503.2).

Incorporate Exposure Pathways Information in Preliminary Alternatives Assessments

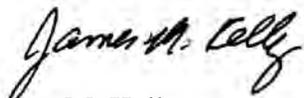
BACWA appreciates that the proposed regulations require an assessment of exposure pathways from a Chemical of Concern in a Priority Product. However, we believe that the responsible entity should provide this information in the First Stage of the AA, rather than in the Second Stage. Early identification of exposure pathways is important so that any inadvertent omissions or inaccuracies can be addressed at the beginning of the AA process. In our experience with pesticide regulatory processes, certain exposure pathways are often inadvertently overlooked by manufacturers and regulatory entities.

If DTSC incorporates our comment above to invite public comment on Preliminary AAs, then any omitted exposure pathways can be identified by interested stakeholders.

Once again, BACWA would like to commend DTSC's efforts in developing these proposed regulations. With our suggested changes, we believe these regulations will help prevent pollution at the source, aid in curbing the skyrocketing costs of remediation and mitigation of environmental impacts, and better enable municipal wastewater agencies to meet their responsibilities to the public. Timely and robust implementation of these regulations is critical – without it, we expect that organizations like our own will end up returning to the legislature to address problem products. California needs strong Safer Consumer Products Regulations that ultimately remove the most pervasive and hazardous chemicals from commerce and our environment, and that promote the creation and use of non-hazardous alternatives.

Thank you for your consideration of our comments. We look forward to participating in the process of furthering green chemistry and safer consumer products in California. If you have any questions, please contact BACWA's Project Manager, Melody LaBella, at (925) 229-7370 or mabella@centralsan.org.

Sincerely,



James M. Kelly
Executive Director

cc: Thomas Howard, Executive Director, State Water Resources Control Board
Jonathan Bishop, Chief Deputy Director, State Water Resources Control Board
Charles Hoppin, Chair, State Water Resources Control Board
Frances Spivy-Weber, Vice Chair, State Water Resources Control Board
Steven Moore, Board Member, State Water Resources Control Board
Tam Dudoc, Board Member, State Water Resources Control Board
Felicia Marcus, Board Member, State Water Resources Control Board

Bruce Wolfe, Executive Officer, San Francisco Regional Water Quality Control Board

Tom Mumley, San Francisco Bay Regional Water Quality Control Board

Dylan Garner, San Francisco Bay Regional Water Quality Control Board

John Muller, Chair, San Francisco Bay Regional Water Quality Control Board

Terry Young, Vice Chair, San Francisco Bay Regional Water Quality Control Board

Shalom Eliahu, Board Member, San Francisco Bay Regional Water Quality Control
Board

Jim McGrath, Board Member, San Francisco Bay Regional Water Quality Control Board

Rameshwar Singh, Board Member, San Francisco Bay Regional Water Quality Control
Board

Gina Solomon, Cal-EPA Deputy Secretary for Science and Health



A Masco Company

THE B. KEVIN JAMES FACILITY

3400 W. Segerstrom Avenue
Santa Ana, CA 92704
Phone 714-545-7101
Fax 714-241-1002
www.behrpaint.com

August 21, 2012

MVB-12020

Krysia Von Burg, Regulations Coordinator
Regulations Section Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

**Re: Behr Process Comments on Safer Consumer Products Draft Regulation
(July 2012)**

Dear Ms. Von Burg:

On behalf of Behr Process Corporation, I respectfully submit the following comments regarding the Department of Toxic Substances Control's draft Safer Consumer Products Regulation dated July 27th, 2012.

Behr Process Corporation is a paint manufacturer with sales throughout the United States, Canada, Mexico and China. In California, Behr and its sister company Masterchem Industries LLC serve retail outlets such as The Home Depot, Lowes, Walmart and True Value Hardware.

I appreciate the opportunity to provide comments on such an important issue. I would like to start by noting that my company appreciates the reduced number of chemicals that will make up the initial Chemical of Concern list. This is more realistic and will make it easier for industry to determine the impact of the green chemistry program on products sold in California. I would also like to thank the department for the process it has used to allow for extensive input from all stakeholders.

My company, however, continues to have concerns with many aspects of the regulations and the impact the program will have on our company and products.

While Behr believes the overall regulation will provide for a safer environment, there are still a number of outstanding issues that will damage our ability to do business in California. The following, at a minimum, must be resolved.

- DTSC must specify a finite number of chemical/product combinations that will be chosen each year as even one COC/POC combination could impact thousands of paint formulations. This is necessary so that provisions can be made for

OTHER BEHR FACILITY

1603 W. Alton
Santa Ana, CA 92704

MANUFACTURING FACILITY

3400 W. Garry Street
Santa Ana, CA 92704

MANUFACTURING FACILITY

3500 W. Segerstrom Avenue
Santa Ana, CA 92704

WEST COAST DISTRIBUTION

1995 S. Standard Avenue
Santa Ana, CA 92707

funding and manpower. An open ended COC/POC numerical range serves no useful purpose.

- Of major concern to our industry is that a very detailed and onerous end-of-life management program is one of the many regulatory response requirements that can be imposed by DTSC. The Green Chemistry statute in S. 25257.1 (b) and(c) provide that DTSC is not authorized ***“to supersede the regulatory authority of any other department or agency”*** or ***“duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article”***. Manufacturers should clearly be exempt from the end-of-life management regulatory response if the manufacturer is participating in an end of life management or product responsibility program mandated by statute in this state, and should not have the burden to request an exemption in such cases. Without such changes, the regulations clearly go beyond the Department’s authority and fail to recognize S. 25257.1’s clear mandate that DTSC cannot supersede or duplicate another agency’s regulatory program.
- The regulation must provide certainty for manufacturers in the area of CBI for all relevant documents and correspondence submitted. What constitutes CBI must be adequately defined in the regulation. The decision as to whether or not CBI is applicable should not be left to the determination of DTSC staff.

Paints and coatings provide both protection and aesthetic appeal, extending the useful life of everyday objects by acting as a protective barrier. Behr Process Corporation is proud to conduct business in the state of California, but it must be noted that it is becoming increasingly difficult to do so. If this regulation were approved as currently drafted, our company will be faced with uncertainty, fiscal hurdles and less opportunity for innovation. Behr hopes that providing these comments will help advance efforts to create a practical, scientifically-based, and legally defensible regulation.

Respectfully,



MICHAEL V. BUTLER
Director - Environmental and Regulatory Affairs
Masco Architectural Coatings Group
3001 S. Yale Street
Santa Ana, CA 92704
Telephone: 714 545-7101, x2304
FAX: 714 241-7589
mbutler@mascocoatings.com

GCREgs@DTSC

From: Robert Xavier Betancourt Junior <badskpr11@me.com>
Sent: Friday, July 27, 2012 11:47 AM
To: GCREgs@DTSC
Subject: Re: Safer Consumer Product Alternatives Proposed Regulation

I guess Dugway Proving Grounds UTAH United States Test & Evaluation Command, never existed according to Veterans Claims. I think it is rather too late now. Yes, there is still Tabun and mustard still buried out there which is exempt from your laws.



October 11, 2012

Debbie Raphael, Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95812-0806

Dear Ms. Raphael,

On behalf of BizNGO, we are encouraged by the progress that DTSC is making towards robust and effective regulations for implementing AB 1879. The basic SCP framework mirrors in large part the best practices among downstream user companies in BizNGO. Our comments are designed to support the development of an AA process that can be effectively implemented by users of chemicals of concern in priority products.

Our most significant concern surrounds the AA process, which due to its complexity may impede implementation and undermine the goal of protecting human health and the environment from exposure to chemicals of concern. In an effort to create a system that strives to reduce the department's resource investments, the opposite happened. The proposed SCP regulations will require significant departmental resources because DTSC will have to:

1. Review, comment on, and approve each Preliminary AA report– and comments may result in extended back and forth process with each responsible entity;
2. Review, comment on, and approve each Final AA report– and comments may result in extended back and forth process with each responsible entity;
3. Review, comment on, and approve each Abridged AA report.
4. Review, comment on, and approve each Alternate Process AA Work Plan.
5. Review and decide upon applications for AA extensions.
6. Issue regulatory response for each AA.
7. Review, interview, and accept applications for accreditation body.
8. Monitor accreditation body.
9. Approve tests developed by the accreditation body.
10. Audit accreditation body.
11. Monitor behavior of assessors and periodically may have to issue a reprimand, suspension, probation or revocation of an assessor.

As the number of AAs grow, so too will the burden on DTSC for reviewing, commenting, and approving each AA report and its consequent regulatory response.

BizNGO proposes that DTSC establish an alternative route to the current proposal – call it the Open Source AA. In the Open Source AA, DTSC would convene a multistakeholder group of content experts, much like the U.S. Environmental Protection Agency's Design for Environment program does in its alternatives assessments. Data needs on alternatives, chemical hazards and exposures, costs, and technical performance would be filled by content experts. The product of the Open Source AA would be an AA for a COC/Priority Product combination. Instead of tens of AAs for a single COC/Priority Product combination, DTSC would have one. Being open source, the data in the AA would be transparent to the fullest extent possible. The Open Source AA would level the playing field for small and medium size

enterprises (SMEs), who would be disproportionately burdened in the proposed AA framework. It would eliminate the need for certified assessors. And it would enable DTSC to issue a single regulatory response, rather than multiple regulatory responses.

BizNGO is especially concerned that in issuing a regulatory response for each AA submitted by each responsible entity DTSC is created an uneven playing field. Some entities will receive longer periods and possibly less stringent regulatory responses than other entities. To create a level playing field, which is what the regulations should accomplish, DTSC needs to release a single regulatory response for each COC/Priority Product combination. All responsible entities filing AA reports for COC/Priority Product combination should have the same time to prepare and submit their reports and the same regulatory response.

An additional benefit of the Open Source AA is it would create a process for stakeholders from businesses, non-governmental organizations, universities, and other government agencies to have input into the AA as well as creating a repository of publicly available information on alternatives to Priority Products. This would alleviate public concerns of the lack of transparency of the AAs.

Questions have been raised about how DTSC would manage an Open Source approach. Since DTSC would be the convener of a group of experts it does not need to hold the technical capacity in house, but would aggregate that technical expertise through the multistakeholder group.

The Open Source AA could operate in parallel to the proposed AA process. Responsible entities would have the option of which route to choose: Open Source AA or the existing proposed AA route (call it the Independent AA). If resources were available, DTSC could outsource the management of the stakeholder process to an external consultant.

Detailed comments to the Proposed Regulations for Safer Consumer Products (SCP), released by DTSC in July 2012 are provided below. Overall, here is a summary of our comments. BizNGO:

- Recommends that the regulations promote transparency as much as possible, including using data already in the public domain and requiring data that can be released publicly without releasing trade secret information.
- Supports in Article 2 the Chemicals of Concern List with the recommendation that it be regularly updated, at least every 24 months to reflect revisions to the reference lists.
- Supports the inclusion in Article 4 of the right to petition for a chemical list as well as a chemical.
- Recommends integrating into Article 5 the option for an Open Source AA as described above.
- Recommends simplifying Article 5 as much as possible, including relying on the Guidance Materials to provide greater detail when needed on what is required for an AA.
- Recommends adding to Article 5, Section 69505.6, that the public have the right to submit comments on the publicly available AA executive summary before DTSC issues a determination notice on the AA.
- Recommends in Article 8 amending Section 69508(a) to simplify initial qualifications pending the establishment of the certification process in Section 69508(b)—there is no need to specify level of education as included in 69508(a).



BizNGO participants are willing to provide more details and explanations of our comments. Please contact me if you have any questions.

Sincerely,

Mark S. Rossi, PhD
Co-Chair, BizNGO
1310 Broadway
Somerville, MA 02144
t) 781.391.6743
e) Mark@CleanProduction.org

BizNGO Note on Government Policy Positions

Participants in BizNGO are all working towards the use of safer chemicals in commerce. Reflecting the diversity of participants in the Working Group, we have a diversity of perspectives on government, NGO and industry initiatives. While BizNGO strives for consensus on all of its policy positions and all participants agree on the government policy issues we address, we may not achieve consensus on the specifics of every BizNGO policy statement.

ARTICLE 1. GENERAL

§ 69501.1 Definitions

BizNGO supports, in particular, the definitions of:

- (11) “Alternative”
- (13) “Alternatives analysis threshold”
- (32) “Hazard trait”
- (34) “Homogenous material”
- (56) “Safer alternative”

(59) Recommend changing "Technically and economically feasible alternative" from

"Technically and economically feasible alternative" means an alternative product or chemical for which:

- (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and
- (B) The manufacturer’s operating margin is not significantly reduced.

To

(61) "Technically and economically feasible alternative" means an alternative product or chemical **for which:**

- (A) **FOR WHICH** the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, **and to meet consumer demand after an appropriate phase-in period;** and
- (B) **THAT IS COMMERCIALY AVAILABLE ON THE MARKET FOR SIMILAR APPLICATIONS.** ~~The manufacturer’s operating margin is not significantly reduced.~~

This definition of technical and economic feasibility cannot be verified in a public and transparent manner—it can only be known by the manufacturer as the operating margin will never be released publicly. Alternatively, if “technical and economic feasibility” is defined as “commercially available” then claims of technical and economic feasibility are publicly verifiable without access to a manufacturer’s private financial information. For a more appropriate definition see the UNEP, Stockholm Convention on Persistent Organic Pollutants, “Report of the Persistent Organic Pollutants Review Committee on the work of its fifth meeting, Addendum, General guidance on considerations related to alternatives and substitutes for listed persistent organic pollutants and candidate chemicals” (3 December 2009), which notes that “The commercial availability of an alternative is an important indicator of technical feasibility.”

69501.4 Chemical and Product Information

BizNGO supports: (d) - Safer Consumer Products Partner Recognition as a means for creating a community of practitioners in support of the program.

§ 69501.5. Availability of Information on the Department’s Website.

(b)(6) A list of all Preliminary AA Reports, Final AA Reports, Abridged AA Reports ...

BizNGO strongly supports the public availability of all Preliminary and Final AA reports. Transparency will be critical to the success of the program. Providing AAs to the public will enhance the quality of AA



submissions and further the development and dissemination of safer alternatives. DTSC should provide incentives for releasing AAs with few to no redactions.

ARTICLE 2. CHEMICALS OF CONCERN IDENTIFICATION PROCESS

§ 69502.2. Chemicals of Concern Identification.

(a) Initial Chemicals of Concern List.

BizNGO supports DTSC using authoritative lists to generate the Chemicals of Concern list. It mirrors processes developed by the states of Maine, Minnesota, and Washington to identify chemicals of high concern as well as how GreenScreen quickly screens for chemicals of high concern to human health or the environment. BizNGO supports the initial Chemicals of Concern List, including the (a)(1)(C) Category 1 endocrine disruptors identified in the European Commission DG Env report.

§ 69502.3. Chemicals of Concern List.

(a) The Department shall post an informational list of the chemicals identified as Chemicals of Concern under section 69502.2(a) on the Department's website within thirty (30) days after the effective date of these regulations. The Department shall **periodically** update the list **AT LEAST EVERY 24 MONTHS** to reflect changes to the underlying lists and sources from which it is drawn, using the procedures specified in subsections (c) and (d).

Given that the authoritative bodies that generate the lists referred to in § 69502.2(a) regularly update their lists, DTSC needs to develop a process for keeping these lists up-to-date.

ARTICLE 3. CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS

BizNGO supports:

- *69503.3 Clearer product prioritization factors and process*
- *69503.4(a)(2)(C)1. – including homogenous material;*
- *69503.4 (f) – the four possible responses expected from responsible entities once a Priority Product is listed; and*
- *69503.5 (b) – products under the AA Threshold need only file an AA Exemption Notification (with supporting documentation).*

§ 69503.4. Priority Products List.

(a)(2)(B)1. If applicable, the component(s) and/or homogeneous material(s) within a component, to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA.

2. For each Priority Product that is a highly durable product, the Department shall in all cases specify the number of component(s) and/or homogeneous material(s) within a component to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA. For each listed highly durable product, the Department shall specify no more than ten (10) components and/or homogenous materials per product every three (3) 22 years.

3. For purposes of subparagraph 2., "highly durable product" means a product that meets all of the following criteria:

- a. The product is assembled from 100 or more manufactured components;
- b. Manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five (5) or more years; and
- c. The product is typically not consumed, destroyed, or discarded after a single use.

The section on highly durable products adds more confusion rather than clarity. At a minimum, delete: For each listed highly durable product, the Department shall specify no more than ten (10) components and/or homogenous materials per product every three (3) years. Although BizNGO recommends deleting all of (a)(2)(B)2.

ARTICLE 4. PETITION PROCESS

BizNGO supports 69504(a) including the provision “to add the entirety of an existing chemicals list to the lists specified in section 69502.2(a).” It is important that the petition process be consistent with section 69502.2(a) and the use of existing authoritative lists.

ARTICLE 5. ALTERNATIVES ANALYSIS

Comments on how the Open Source AA could be specified:

§ 69505.2. Analysis of Priority Products and Alternatives

(c) A responsible entity may use an Alternate AA process that differs from the process specified in sections 69505.3 and 69505.4 or an Open Source AA.

(1) Alternate AA Process [as described in 69505.2(c)(1)-(4)]

Insert New section

(2) Open Source AA Process

(A) The Department shall convene an Open Source AA that meets the requirements of section 69505.5 for each COC/Priority Product combination.

(B) The Open Source AA shall be open to participation by interested stakeholders, including, but not limited to responsible entities, non-governmental organizations, academic institutions, manufacturers, trade associations, and individuals.

(C) Open Source AAs shall not be subject to the requirements of section 69508.

Comments on improving proposed Article 5 regulations:

§ 69505.1. Alternatives Analysis: General Provisions

- 69505.1 (c) and others – BizNGO supports additional consortia completing AAs on behalf of companies or industries.
- 69505.1 (g) – BizNGO supports allowing the simple removal of the Chemical of Concern from a product to only require submission of a Chemical of Concern Removal Notice in lieu of doing an AA.

§ 69505.2. Analysis of Priority Products and Alternatives

(b) After completion of the first four (4) steps of the first stage of the AA, under subsections (b)(1) through (b)(4) of section 60505.3, a responsible entity that determines a functionally acceptable

alternative is not available or feasible may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if all of the following requirements are met:

- (1) The responsible entity summarizes, in the Abridged AA Report, the first stage AA findings in conformance with the applicable requirements of section 69505.5;
- (2) The responsible entity identifies the factors relevant for comparison of alternatives, as specified in section 69505.4(a), and summarizes, in the Abridged AA Report, its findings with respect to section 69505.4(a) in conformance with the applicable requirements of section 69505.5;
- (3) The responsible entity submits an Abridged AA Report to the Department by the due date specified in section 69505.1(c)(3)(A);
- (4) The responsible entity specifies in the implementation plan included in the Abridged AA Report the milestones and dates for implementation of proposed regulatory responses, which shall, at a minimum, include the regulatory response required under section 69506.9;
- (5) The responsible entity shall submit an executive summary of the Abridged AA Report with no redactions to the Department that sufficiently explains the lack of an alternative to the Priority Product;
- (6) The Department shall post the Abridged AA executive summary on its website and shall provide 60 days for public comment on the Abridged AA executive summary; and
- (7) The Department shall review the public comments and review data on available alternatives and shall issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. If the Department determines that an Abridged AA report is deficient, that alternatives are on the market for the Priority Product, the Department shall require the responsible entity to comply with 69505.3, 69505.4, and 69505.5 or the Department shall issue a regulatory response.

BizNGO is concerned that Abridged AAs may be submitted when technically and economically viable alternatives are already on the market. Given this concern, it is critical that the department allow public comment on Abridged AAs before they are finalized and that the department be given the authority to require first and second stage AAs as well as the authority to enact a regulatory response in response to a deficient Abridged AA.

§ 69505.4. Alternatives Analysis: Second Stage.

- (a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.
 - (2)(A) Multimedia life cycle impacts and chemical hazards for chemical ingredients known to be in the Priority Product and the alternatives being considered based on available information *If DTSC chooses to leave “chemical hazards” in this sentence it should explain why, given that chemical hazards are addressed in the AA First Stage. Otherwise “and chemical hazards” should be removed from the second stage as it was addressed in the AA first stage.*
 - (a)(1)(B) – BizNGO supports within Second Stage AA retaining the original Chemical of Concern as a baseline for comparison for assessing adverse impacts.
 - (a)(2)(C) Economic impacts
BizNGO supports Economic Impacts as written in this section. It makes sense that the economic impact assessment should be of greater detail if the responsible entity uses economic impacts to justify continued use of the Priority Product.
- (b) **Step 2, Comparison of the Priority Product and Alternatives.**
The responsible entity shall use available quantitative information and analyses, supplemented by available qualitative information and analysis, to evaluate and compare the Priority Product

and each of the alternatives under consideration with respect to each relevant factor and associated exposure pathways and life cycle segments identified under subsection (a). The responsible entity shall compare each alternative with the Priority Product and with each of the other alternatives being considered.

The responsible entity shall identify and/or document, as appropriate, all of the following information:

- (1) Quantitative metrics, where available and appropriate, for each of the relevant factors identified under subsection (a)(2);
- (2) Qualitative metrics for any relevant factors for which quantitative metrics are not available or appropriate;
- (3) Available data for each metric for the Priority Product and each alternative being considered;
- (4) Any absent or conflicting data regarding a relevant factor, and either or both of the following, as appropriate:
 - (A) Available data that is most protective of public health and the environment, unless there are sound methodological reasons for rejecting such data; and/or
 - (B) A value for the metric, using a method for dealing with data uncertainty due to absent or missing data that has been adopted by an authoritative organization, as defined in subsection (b) of section 69401.2, or generally accepted in peer reviewed literature;
- (5) A description of the performance of the Priority Product and each alternative, with respect to each of the relevant factors;
- (6) Appropriate qualitative and/or quantitative relative weights for the relevant factors, and the rationale for the assignment of the relative weights;
- (7) An evaluation of the overall performance of each alternative as compared to the Priority Product and the other alternatives, including discussion of the impact of the weight placed upon the relevant factors, the rationale for choosing the particular method for determining the overall evaluation, and the sensitivity of the comparative evaluation to data uncertainty; and
- (8) Any other known evaluation of the Priority Product or one or more of the alternatives that comes to different conclusions, regarding the relative overall performance or public health and/or environmental impacts, and the reasons for the difference in the conclusions.

BizNGO recommends deleting the above 69505.4 (b)(1-8): this level of detail is appropriate for the Guidance Materials and should not be included here; especially since this level of analysis is already summarized in 69505.4(a)(2)–“The responsible entity shall collect and use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools.”

- (c) Step 3, Alternative(s) Selection Decision –
The responsible entity shall select the alternative(s) that will replace or modify the Priority Product, unless the decision is to retain the existing Priority Product. The selection of an the alternative(s) or the decision to retain the Priority Product shall be based on and supported by the comparative analysis conducted under subsection (b).
DTSC should recognize that a business may want to use multiple alternatives. This is especially true of a business with multiple suppliers, which may want to allow the suppliers to select from / develop different alternatives.

69505.5. Alternatives Analysis Reports.

- (b) Executive Summary
BizNGO supports Executive Summaries including sufficient data to publicly convey the rationale for the selection decision.
- (g) **Scope of Relevant Comparison Factors.** The Final AA Report must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant, under section 69505.4(a), for evaluation and comparison of the Priority Product and its alternatives. **For each factor, exposure pathway, and life cycle segment determined not to be relevant, the Final AA Report must explain the rationale and identify, and explain the pertinent findings of, the supporting information for this determination.**
The Final AA Report should focus on the hot spot areas identified versus those that are not considered relevant. The level of detail requested by the Department here is out of context with the Department's ability to evaluate this data as well as with the relevance of that data to a regulatory response.

69505.6. Department Review and Determinations for AA Reports.

- (b)(1) Within ~~sixty (60)~~ **thirty (30)** days of receiving a Final AA Report, the Department shall **POST THE PUBLICLY AVAILABLE EXECUTIVE SUMMARY ONLINE FOR PUBLIC REVIEW AND COMMENT. THE PUBLIC WILL HAVE 45 DAYS TO SUBMIT COMMENTS TO THE DEPARTMENT EVALUATING THE SUFFICIENCY OF THE AA FOR SUPPORTING THE RESPONSIBLE ENTITY'S DECISION. THE DEPARTMENT SHALL REVIEW COMMENTS AND** review the AA Report for compliance with the requirements of this article, and shall issue a notice of compliance, a notice of deficiency, or a notice of ongoing review.
BizNGO is deeply concerned that the public has no opportunity to provide input into the AAs. Once a COC/Priority Product combination is made DTSC closes its doors to public input. This is a huge deficiency in Article 5 given the level of knowledge of technically viable alternatives outside of the responsible entities. Therefore, we recommend that the public have the right to submit comments on the publicly available AA executive summary before DTSC issues a determination notice on the AA.

Article 6. Regulatory Responses

69506 – BizNGO supports the goal of preferring regulatory responses that provide high levels of inherent protection.

Article 8. Accreditation Bodies and Certified Assessors

§ 69508. Qualifications and Certification for Assessors.

(a) **PRIOR TO ESTABLISHING THE TRAINING AND CERTIFICATION PROGRAM IN 69508(b), ASSESSORS SHALL COMPLETE AN AA TRAINING DELIVERED BY THE DEPARTMENT OR ITS DESIGNEE.** An individual in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, shall meet both of the following requirements:

~~(1) Possess a Bachelor's degree with a major in a scientific or engineering field from an accredited college or university.~~

~~(2)(A) Have the equivalent of two (2) years of professional experience performing AAs and/or working in a scientific or engineering field.~~

~~(B) Post graduate work in the performance of AAs and/or in a scientific or engineering field, while attending an accredited college or university, may be substituted on a year for year basis for the experience required under subparagraph (A).~~

(b) On and after the date two (2) years after the effective date of these regulations, an individual in charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, shall successfully complete an assessor training program that is developed and delivered by an accreditation body, successfully complete an exit exam that meets the requirements of section 69508.2(c)(5), and meet all of the following requirements: ...

The detailed academic qualifications for assessors are unnecessary. For example, the successful Massachusetts Toxics Use Reduction Planners program has no academic requirements. BizNGO recommends deleting the academic qualification requirements listed in Section 69508(a). These qualifications are so stringent that the majority of current experts in the field would not meet them. In their stead BizNGO recommends an initial training course by the department or its designee. Thereafter meeting the requirements of Section 69508(b) will be sufficient for qualification.



2828 University Avenue SE, Suite 200
Minneapolis, MN 55414

1020 19th Street NW, Suite 600
Washington, D.C. 20036

330 Townsend Street, Suite 205
San Francisco, CA 94107

October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
E-mail: gcregs@dtsc.ca.gov

Re: Proposed California Safer Consumer Product Regulations

Dear Ms. Von Burg:

The BlueGreen Alliance is a national partnership of 10 labor unions and 4 environmental organizations representing more than 15 million members and dedicated to expanding the number and quality of jobs in the green economy. We believe that green chemistry and the production of safer products can become a major source of those jobs in California and across the United States. So we strongly support the Department of Toxic Substances Control's Green Chemistry Initiative and the proposed regulations on safer consumer products. The finalization of the Safer Consumer Product Regulations will move us towards a future where the health of workers and the public are protected through substitution and elimination, the highest levels of the hierarchy of controls.

The 14 partners of the BlueGreen Alliance are gratified that the revised regulations include a definition of adverse public health impacts that now specifically includes the sentence, "Public health includes occupational health." 69501.1 (6) Similarly, we were glad to see that the July revisions added "workers with greater exposures due to the nature of their occupation" to the definition of sensitive sub-populations. 69501.1 (58)

We believe that the creation of a comprehensive and unranked list of Chemicals of Concern will be extremely valuable. 69502.2 The BlueGreen Alliance also strongly supports the elimination of a single de minimis level for exemption and the removal of regulatory language that set a default Alternative Assessment threshold. Sound science guides the new chemical-by-chemical approach. 69503.5

We also support the recommendations of Worksafe that DTSC add one or more of the authoritative list of asthmagens to the foundational documents for the Chemicals of Concern; that the agency review the provisions of the Cal/OSHA Hazard Communication Standard to make sure that the two regulations are aligned;



and that material safety data sheets (MSDSs) or safety data sheets (SDSs) be added to the lists of information that must be provided in Sections 69505.5(e) and 69506.4.

We add our voice to the many who have asked why the proposed regulations exclude products made in California but not sold in the state. *69501(b)(3)* While we recognize that there may be jurisdictional concerns, we would ask that they be addressed so that California workers who make products for exclusive use outside of the state and the communities around those manufacturing sites are not less protected from chemicals of concern than other Californians.

Finally, thank you for the hard work that went into the drafting of this regulation. The partners of the BlueGreen Alliance look forward to working together with you on its implementation.

Sincerely,

A handwritten signature in black ink, appearing to read "Charlotte Brody".

Charlotte Brody, Associate Director for Health Initiatives
BlueGreen Alliance

A handwritten signature in black ink, appearing to read "Lisa Hoyos".

Lisa Hoyos, California State Director
BlueGreen Alliance

Rob Harrington, Ph.D.
Director, Regulatory & Safety
Blyth, Inc.
603 Kingsland Drive
Batavia, IL 60510

BLYTH

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation

Dear Ms. Von Burg:

On behalf of Blyth, Inc., we respectfully submit the following comments relative to the Department of Toxic Substances Control's proposed Safer Consumer Product Alternatives Regulation. Blyth is a manufacturer of consumer products including candles, air care and personal care products.

We believe DTSC is proposing a regulatory scheme far in excess of that what it needs and what it can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

One of the most concerning aspects of the proposed regulation as currently drafted is the degree of freedom the Department has to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation.

This regulation is extremely complex, and will be exceptionally costly to both industry and the taxpayer. While we believe our products do not pose a health concern to our customers, if we were required to conduct an alternatives assessment of our products, the cost of doing so would prohibit us from continuing sell the product in the State of California. Even a medium-sized company like ourselves would be stretched severely to have to try to comply with this regulation. We believe there are other appropriate methods to improve consumer product safety.

It is conceivable that this regulation could be hijacked by special interest groups and those with a political agenda to target certain products or chemicals which they perceive as unsafe. The result could be a disastrous confrontation between the various groups resulting in a quagmire of legal and regulatory issues. Unfortunately, California has chosen this course of action in spite of the fact that no other regulatory authority in the world sees this as a viable alternative. In order to avoid a regulatory gridlock this process has to be clear, transparent, and relatively straightforward. We urge you to reconsider some of the requirements in this regulation and to clearly specify what is required.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement. The cost will ultimately be passed along to the consumer and taxpayer.

The intent of the statute is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will cause havoc in the consumer products market.

We appreciate your consideration of our concerns.

Sincerely,

Rob Harrington, PhD.
Director of Safety and Regulatory
Blyth, Inc.

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

**BREAST
CANCER
ACTION**

October 10, 2012

Krycia Von Burg
Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Dear Ms. Von Burg:

As Executive Director of Breast Cancer Action, I am writing to offer comments to the Department of Toxic Substances Control's draft regulations to implement a Safer Consumer Products program under the authority of AB 1879.

Breast Cancer Action (BCAction) is a national education and advocacy non-profit organization working to address and end the breast cancer epidemic. Because Breast Cancer Action's work is led by our members who are living with and at risk of breast cancer, our organization strongly supports regulation that addresses our concern for the impacts of toxic chemical exposure.

Toxic chemicals can have devastating impacts on human health and the environment. BCAction strongly advocates for regulation that supports a precautionary principle with regard to the risk that chemical exposure poses, and that addresses cumulative exposure to a variety of hazardous chemicals, both of which are necessary to protect public health.

BCAction supports DTSC's implementation of a Safer Consumer Products program, and we look forward to this program's implementation without unnecessary delays. In addition to this letter, Breast Cancer Action supports the more thorough and detailed comments to the draft regulations submitted by Californians for a Healthy and Green Economy (CHANGE).

Thank you for your consideration of this letter, and for the opportunity to comment.

Sincerely,



Karuna Jaggar
Executive Director
Breast Cancer Action



October 10, 2012

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Comments on the California Department of Toxic Substances Control – Proposed Regulation: Safer Consumer Product Alternatives

Dear Ms. Von Burg:

The California Attractions and Parks Association (CAPA) would like to express our concern over aspects of the proposed Department of Toxic Substances Control (DTSC) Regulations for Safer Consumer Products Alternatives (SCP).

CAPA is a trade association which represents virtually all of California's theme, amusement and water parks. Our members directly employ more than 125,000 workers; generate more than \$12 billion in annual state commerce; and form the economic foundation for communities around the state. Our members range from world renowned destination resorts, to small family-owned entertainment centers.

Our industry provides a wide variety of entertainment offerings and a wide variety of retail sales products manufactured locally, nationally and internationally.

We agree with, and support, the comments also submitted by the Toy Industry Association (TIA) and the Green Chemistry Alliance, of which CAPA is a member.

In addition to the detailed analysis and comments provided by those organizations, we would also like to raise the following issues:

California's Great America

Children's Fairyland

Disneyland Parks
and Resorts

Funderland

Gilroy Gardens Theme Park

Golfand Entertainment
Centers

Knott's Berry Farm

LEGOLAND California

Pacific Park

Palace Entertainment

Pixieland Amusement Park

Redwood Valley Railway

Santa Cruz Beach
Boardwalk

SeaWorld Parks
and Entertainment

Six Flags Discovery
Kingdom

Six Flags Magic Mountain

Sonoma Train Town

The Wave Water Park

Universal Parks and Resorts

Water World California

Wild Rivers Water Park

*Partial list

1. Retailers should not shoulder the burden of SCP regulations and compliance:

Compliance with the proposed regulations is simply impossible for most retailers. Retailers should not be included in the group of “responsible parties” under the regulations. Currently, the SCP regulations set up a tiered joint liability scheme where manufacturers (the product manufacturer or entity that controls the specifications and design of, or use of materials in, the product) have the primary responsibility for compliance. The importer has responsibility for compliance if the manufacturer fails to comply. Finally, the retailer must comply if the manufacturer and importer fail to comply, and the DTSC lists their noncompliance on the “Failure to Comply” list.

However, retailers do not have the resources or capabilities to comply with SCP regulations. Retailers do not generally know the chemical composition of the various products they sell; they have no visibility to the supply chain of the manufacturer; and they cannot specify what chemicals or components will be included in the products.

This simply places an unfair and impossible burden on most retailers. Compliance would require resources that retailers do not have, and cannot afford to obtain.

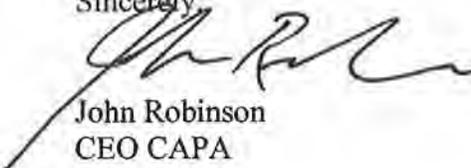
2. Alternative analysis exemption notification: Requiring manufacturers to apply for a small quantity exemption is counter to the spirit and intent of the regulations, which acknowledge that minimal concern exists for such extremely small levels of a chemical in a product. Additionally, the process is unnecessarily cumbersome and requires the release of proprietary data, which may become public, for products that are not a priority and pose no human health or environmental concerns.

3. Inaccessible components: For assembled products where chemicals of concern do not come in contact with humans or the environment, “inaccessible components” should be clearly defined and removed from prioritization. An example of an inaccessible component is lead solder on embedded printed circuit boards.

4. Contaminant definitions: Contaminant is referenced in Section 69503.5(c) (1) (A) and (C), but is not defined in the regulations. Contaminant should be clearly defined in the regulation and such definition should not be more restrictive than the definitions used in other states, such as Washington and Maine.

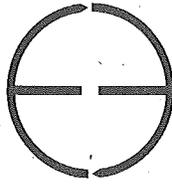
We feel the true scope, cost and practicality of these proposed regulations have not been fully considered. We urge the DTSC to take a more comprehensive and measured approach which recognizes the very limited ability of retailers to address the compliance issues raised in the proposed regulations.

Sincerely,



John Robinson
CEO CAPA

Walter McGuire
CHAIRMAN
Jose Mejia
VICE-CHAIRMAN
Gerald D. Secundy
PRESIDENT
William J. Quinn
CHIEF OPERATING OFFICER
Steve Gross
TREASURER
Randy Fischback
SECRETARY



California Council for Environmental and Economic Balance

100 Spear Street, Suite 805, San Francisco, CA 94105 • (415) 512-7890 • FAX (415) 512-7897

BOARD OF DIRECTORS

Linda Adams
Bob Antonoplis
William T. Bagley
Robert Balgenorth
Michael Barr
Jack Bean
Mike Beasley
Ed Bedwell
Joseph C. Bellas
Russ Burns
Steve Burns
Ken Casarez
John Chillemi
Michele Corash
Tim Cremins
Hal Dash
Bill Devine
Cesar Diaz
Greg Feere
Randy Fischback
Steve Gross
Michael Hertel
Fred John
James (J.P.) Jones
Kenneth L. Khachigian
John T. Knox
Kristen Korbus
Kirk Marckwald
Walter McGuire
Sunne McPeak
Jose Mejia
Cindy Montanez
Richard Morrison
Cressey Nakagawa
Joe Nuñez
George Piantka
Art Pulaski
Matt Rezvani
Mike Roos
Lanny Schmid
Gerald D. Secundy
Dan Skopec
Don Solem
Katherine Strehl
Minnie Tsunezummi
Victor Weisser

CONSULTANTS

Kendra Daijogo
THE GUALCO GROUP, INC.
Jackson R. Gualco
THE GUALCO GROUP, INC.
Robert W. Lucas
LUCAS ADVOCATES

Gov. Edmund G. "Pat" Brown
FOUNDING CHAIRMAN 1973

www.cceeb.org

October 11, 2012

Director Debbie Raphael
California Department of Toxic Substances Control
State of California
1001 I Street
Sacramento, CA 95812
(Submitted via email)

Subject: Proposed Regulations for Safer Consumer Products Alternatives

Dear Ms. Raphael:

The California Council for Environmental and Economic Balance (CCEEB) is a non-partisan, non-profit coalition of business, labor and public leaders that advances strategies for a strong economy and a healthy environment. On behalf of CCEEB, we want to thank the Department of Toxic Substances Control (DTSC) for this opportunity to comment on the Proposed Regulation on Safer Consumer Product Alternatives. CCEEB has reviewed this 78-page draft regulation and offers the following comments.

CCEEB agrees with the drive for safe and continually safer consumer products. Our members have extensive experience in continuous review and testing of product formulations to maintain the safest consumer products available. As opposed to other countries, the US product liability law provides a strong incentive to assure that products that enter the stream of commerce are safe and durable and do no harm. When defects are detected, products are recalled. However, this process is extremely complicated with many variables, both theoretical and real and it takes significant time to thoroughly review and assure that the product formulation is safe and durable for its purpose, that there is an adequate supply of necessary materials for the formulation and that there is an adequate supply of replacement parts to assure that the product can be properly maintained over time.

In general CCEEB is concerned that because of this proposed rule's considerable breadth and lingering lack of specificity, that in its current form it will likely give rise to serious implementation issues, potentially significant economic consequences and potential legal challenges, including potential exposure of the state to liability claims, and warranty claims unless revisions are considered.



CCEEB shares many of the same concerns expressed in the twelve-page, September 2012, European Union detailed comment letter.

Regulatory Overreach and Potential Job Leakage – A Complete Economic Analysis of this Draft Regulation Needs to be performed

We note that this draft includes “occupational health” within the broader context of public health. We suggest that this reference should be removed.

We believe that it would be regulatory over-reach for DTSC to place itself into the duties and responsibilities of the Department of Industrial Health and CALOSHA. We believe that such an expansion of regulatory role is outside the scope of both AB 1879 and SB 509 (statutes of 2008) and specifically improper under Health and Safety Code §25257.1(b).

In addition, we are concerned that if this consumer product regulation does reach beyond consumer products into the manufacturing process of bulk chemicals in California, that are already subject to regulation under federal and state Occupational Safety and Health Administration regulations, that this new duplicative regulatory reach could chase these manufacturing jobs out of the state.

CCEEB is also concerned about the potential unequal treatment of affected economic operators, which may result in small and medium size entities exiting the California market because of the unnecessary complexities in this draft regulation.

We believe that any economic analysis of potential impacts of this draft regulation would have noted the potential for this job leakage and other potential detrimental market impacts to occur. We further believe that a complete and thorough economic analysis of all of the potential impacts of this proposed rule is not only warranted, but needs to be performed before rule adoption. This proposal is far more than a simple process. It will require actions that can be anticipated and evaluated before adoption. Certainly, the entities that it will affect will anticipate required actions and act accordingly.

Guidelines for the Alternative Assessment Required by this Draft Regulation Must be Included in the Regulation

It is troubling that this draft regulation contains no specifics on how to conduct an Alternative Assessment that is central to this proposal. Where is this guidance going to come from, if it is not part of this regulation? How will Alternative Assessments that are submitted to the department be evaluated?

We are aware that California is part of an eight state effort funded by a small grant from the USEPA to the State of Washington to develop such guidelines. If California wants to use such an effort to inform the development of its own regulatory requirements for the preparation of

Alternative Assessments that would be acceptable, if they were outlined in this proposed regulation. They are not in this proposal.

We believe that any DTSC reliance upon the guidelines being developed by the State of Washington to judge the adequacy of Alternative Assessments submitted to the Department, without first subjecting those potential guidelines to review and comment through the California regulatory process, would violate the California Administrative Procedures Act as the application of underground regulations.

When properly considered as regulations, such guidelines should be objective and use specific criteria to identify risks that are then evaluated with appropriate exposure models. The lack of clarity surrounding alternative assessments creates unnecessary complexity and high administrative burdens related to its implementation. Furthermore, the accreditation and certification systems, as described, appear to be unnecessarily complex without informed details on how an alternative assessments program will be implemented.

The Draft Regulation Does Not Specify the Amount of a Chemical of Concern That Would Trigger an Alternative Assessment

The draft regulation does not establish a threshold value of the amount of a chemical of concern in a product that would necessitate the preparation of an Alternative Assessment. There has been some discussion that the laboratory “detection limit” for a chemical of concern would be appropriate. We disagree that a laboratory detection limit is appropriate for this determination. Present day laboratory detection limits are far below any regulatory standard for health or environmental protection. We recommend that the department designate a de minimis level well above the laboratory detection limit of a chemical of concern that would require that an Alternative Assessment be performed. Any criteria or process to determine this threshold must be technically feasible, cost-effective, workable and based upon risk considerations.

Sole Presence of a Chemical is Not Appropriate Criteria to Require a Change to an Alternative

Industry routinely performs design reviews and alternatives assessments during the product development process. Materials are substituted as data and tests warrant; likewise, safety and performance must not be compromised. Real exposure and actual risk must be present to require a substitution. This proposal should, but does not, exempt materials that are inaccessible to the product user. Nor does the proposal differentiate between intentionally added materials and unavoidable contaminants. Contaminants may be introduced during the manufacture or simply arise as a finished product ages.

We are concerned that many will misconstrue the purpose of this list of chemicals of concern. These include: companies in the supply chain, governments, NGOs, and perhaps most importantly, by members of the general public who cannot be universally expected to understand complex technical issues, leading to unfounded fear. It is very likely that the chemicals identified through this process by inclusion in the list of Chemicals of Concern will have a stigma attached to them that will cause their use to be unnecessarily challenged or questioned,

even though the chemicals may have already undergone an assessment or be safe in many specific applications

Assessors Will Need Product Development or Manufacturing Experience

This proposal places the State and assessors in the position to second-guess industry's comprehensive product development process. For this reason assessors should have product development or manufacturing experience that is not recognized in this proposal.

Further Legal Analysis and Evaluation is Needed

CCEEB believes that there are several significant legal issues that should be rigorously reviewed.

Since this proposal uses the Proposition 65 list as well as others, there will likely be Proposition 65 issues that will come up during this regulation's tenure. These issues usually arise through litigation or threat of litigation. CCEEB is unsure if these issues have been considered.

CCEEB concurs with other commenters that a complete California Environmental Quality Act (CEQA) analysis is legally required and should be performed on this proposed regulation.

We also suggest that the application of product liability laws be reviewed to determine the level of potential state liability risk because of an unanticipated product malfunction due to a state-mandated product change. In this regard, DTSC must be mindful of its state liability for the Stringfellow Superfund Site arising from state-mandated actions.

Similarly, the legal implications of state-mandated product formulation changes on product warranties should also be reviewed and taken into account.

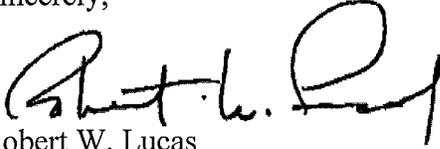
Conclusion

This proposed regulation would enact sweeping new requirements on industry's product formulation programs. Though many of the goals have virtue, the insertion of state employees into a decision-making role in the choice of chemicals in private industry products raises many issues of qualification, readiness and appropriateness of this approach. Significant care must be given to be certain that all ambiguities have been addressed and that the final proposed rule is complete and indeed ready for adoption.

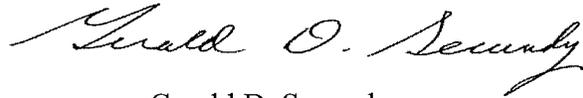
CCEEB does not believe that this regulation is ready for adoption. We believe that it is incomplete and in many instances, vague. We also believe that it has not been subjected to the necessary scrutiny of CEQA, a thorough economic impact analysis nor a comprehensive legal assessment. We appreciate that DTSC would like to accelerate the finalization of this rule, but we counsel that more time and reflection of potential impacts be considered.

Thank you for this opportunity to comment, if you have any questions please contact Bob Lucas at 916-444-7337.

Sincerely,



Robert W. Lucas
Waste and Water Quality Project Manager



Gerald D. Secundy
President

cc: The Honorable Michael Rubio, California State Senate
The Honorable Luis A. Alejo, California State Assembly
Nancy McFadden, Executive Secretary to Governor Brown
Cliff Rechtschaffen, Senior Advisor to Governor Brown
Michael Rossi, Senior Advisor to Governor Brown
Matthew Rodriguez, Secretary, California Environmental Protection Agency
Odette Madriago, Chief Deputy Director, DTSC
Jeff Wong, Chief Scientist, DTSC
Krycia Von Burg, Regulations Coordinator, DTSC
The Gualco Group



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
Notification of technical regulations

Brussels,
LK/nv – entr.c.3(2012)1225848

E-MAIL

To: TBT Enquiry Point of the United States **E-mail:** ncsci@nist.gov

Copy Ms M P Nicora
EU Delegation of the United States

From: Mr Giuseppe Casella **Telephone:** + 32 2 295 63 96
EU-WTO-TBT Enquiry Point **E-mail:** eu-tbt@ec.europa.eu

Number of pages: 1 + 12

Subject: G/TBT/N/USA/727 – DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS" – EU comments

Message:

Dear Sir or Madam

Please find attached the comments from the European Union on the above-mentioned notification.

Could you please acknowledge receipt of this e-mail? Thank you.

Yours faithfully

Giuseppe Casella
Head of Unit

Contact: Mr László Kojnok
Telephone: (32-2) 295 09 08.
E-mail : eu-tbt@ec.europa.eu

**COMMENTS FROM THE EUROPEAN UNION CONCERNING
NOTIFICATION G/TBT/N/USA/727**

**DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL
(DTSC) ON "SAFER CONSUMER PRODUCTS"**

The European Union (EU) would hereby like to submit comments on the draft Regulation of the California Department of Toxic Substances Control (hereinafter "DTSC") on Safer Consumer Products, which was notified on 8 August 2012.

The EU would like to thank the US authorities for the notification of the draft Regulation, as this allows the EU and other trade partners of the US to comment on it. This draft establishes a number of direct obligations for producers of chemical substances, mixtures and articles, as soon as the substance, mixture or article is listed as a so called "Priority Product" and contains a so-called "Chemical of Concern". Whilst the draft Regulation does not yet list specific products or specific substances, all the conditions and requirements that companies eventually have to comply with are already contained in the draft Regulation and cannot be changed at a later stage.

The EU will first provide general observations on the principles of the draft Regulation and then offer more detailed comments on the text itself.

General Comments

First of all, the EU would like to underline that it fully shares the objectives of the draft Regulation, namely to achieve a high level of protection of human health and the environment by substituting the most hazardous chemicals with safer alternatives and adequately informing users about the risks from chemicals. To this effect, the EU has put into place, among others, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as "REACH" and "CLP" Regulations).

The EU would, therefore, also like to share with the Californian authorities some of the experience gained with regard to the adoption and application of the above-mentioned Regulations.

With regard to the main principles of the draft Regulation, the EU is concerned about three issues, which will be explained in more detail below:

- potential for unequal treatment of economic operators,
- extreme complexity of the proposed alternative assessment procedure and high administrative burdens related to its implementation raising concerns about their compatibility with Article 5.1.2 of the TBT Agreement and

- creation of a highly specific accreditation and certification system which seems to be disproportionate in view of Article 5.1.2 of the TBT Agreement and moreover could potentially disadvantage manufacturers located in third countries (Article 5.1.1 of the TBT Agreement).
- 1. Several provisions of the draft Regulation have the potential of discriminatory effects among the so-called "responsible entities" (i.e. manufacturers, importers or retailers), both at the beginning and the end of the process.

For example, under § 69501.4 (a) (3) and (4) of the draft Regulation, DTSC can request a responsible entity or a chemical manufacturer or importer to make existing information available to DTSC within a specified time frame, or even oblige an economic operator to generate new information and provide it to DTSC. Failure to do so results in the responsible entity being "black-listed" on the 'Response Status List' of DTSC in accordance with § 69501.4 (c). However, a responsible entity not known to DTSC or not having been asked to provide information will not appear on this list, without the stigma of having failed to respond to requests from DTSC. Hence, solely the fact of being known or not known to DTSC will potentially lead to discriminatory consequences for responsible entities.

According to §69503.7 responsible entities must submit priority product notifications, following the listing of the priority products concerned by DTSC. However, if companies do not identify their products themselves, they will not be known to DTSC and will be spared the burdensome consequences of conducting an alternative analysis and of implementing regulatory response(s). The EU would like to ask how DTSC will ensure that all duty holders will be treated equally given that at the time of listing priority products, DTSC will not have a complete market overview.

According to § 69505.1 (f), a responsible entity may fulfil its requirements to conduct an alternative analysis (hereinafter "AA") by submitting to DTSC a report for a previously completed AA for the priority product. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection). Consequently, the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

After having conducted the alternative analysis, different responsible entities marketing the same (or very similar) priority product(s) with the same chemicals of concern, can come to very different results – some being able to replace the priority product or chemical of concern, while others might not and hence propose different 'regulatory responses'. Whilst DTSC will review the proposed regulatory responses, it is not clear from the draft Regulation that DTSC will actually require in such circumstances that all entities have to replace the product or chemical of concern, or whether DTSC will indeed impose one or several regulatory response(s), which could again be different for the responsible entities.

Lastly, some of the regulatory responses that DTSC can impose also have the potential of having very different consequences for responsible entities, in particular when these are small or medium-sized enterprises (SME) or located

outside California. For example, an SME (or an importer on behalf of an SME manufacturer outside California) selling only relatively few priority products will never be able to set up the very demanding and costly End-of-Life Management Requirements described under § 69506.8; whilst this might well be feasible for a big company imposing this regulatory response it would, *de facto*, amount to a ban for the SME producer. Likewise, DTSC can impose the regulatory response to fund research and development projects for the advancement of Green Chemistry and Green Engineering (§ 69506.9), but there is no indication as to which amount(s) will be involved. In order to avoid disadvantages for SMEs, there should preferably be a link with a certain percentage of the turnover made with the priority product in question.

2. The EU would like to elaborate below on the provisions of the draft Regulation related to the alternative assessment procedure and the administrative burdens related to the implementation, with respect to which it has concerns about their compatibility with Article 5.1.2 of the TBT Agreement.

First of all, the EU would like to note that the US Government is taking strong efforts in recent years to reduce and avoid administrative burdens for businesses. Accordingly, the Californian proposal seems to be at odds with the US 'smart regulation' policies and principles. In particular, the EU would like to refer to Executive Order 13563 of January 18, 2011 on Improving Regulation and Regulatory Review, which notably provides that the US regulatory system must: promote predictability and reduce uncertainty; identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends; take into account benefits and costs, both quantitative and qualitative; ensure that regulations are accessible, consistent, written in plain language, and easy to understand and measure, and seek to improve, the actual results of regulatory requirements.

The alternative analysis (AA) as described in Article 5 is excessively complex as the range of factors to be analysed is extremely broad and will require huge amounts of data that might be very difficult to obtain. In particular, responsible entities that are SMEs might well not be able to find all relevant data, not even with the help of a certified assessor – or, if so, only at very high cost compared to the company's financial means. It is regrettable that in its analysis of economic impacts DTSC has not actually analysed a few case studies (e.g. a simple case of a chemical mixture and a more complex case of an article composed of many components) to actually demonstrate that the prescribed AA is feasible within the given amount of time and at what costs¹ (even leaving aside the actual costs for substituting the chemical of concern). This type of analysis for processes and procedures was conducted by the EU before REACH was adopted - in fact, this had been strongly called for by economic operators and third countries, including the US, and this has ultimately helped to modify a number of provisions in

¹ In fact, in the attachment to the Economic and Fiscal Impact Statement, DTSC merely states on pages 4 and 5 that costs could vary between a few thousand dollars and hundreds of thousands of dollars, which is not very informative. Analysis of a few real case studies as for example conducted in the electronics industry and/or the US EPA Design for the Environment Programme would probably have provided more concrete estimates, both for costs and the necessary time.

REACH in comparison to how they were originally envisaged². The EU would therefore call on DTSC to reflect on ways that the AA can be simplified, for example in the guidance that is to be developed in accordance with § 69505, or by designating a more limited and specific range of parameters to be analysed when listing a priority product and chemical(s) of concern according to § 69503.4.

The numerous (and in themselves already rather complex) notifications and reports to be submitted by the responsible entities to DTSC, their evaluation by DTSC (within rather short periods of time), the various notices of approval or deficiencies, further submissions and updates of already submitted AA reports, as well as possibilities for administrative disputes etc. could often be duplicative and bear the risk that DTSC might quickly become overwhelmed by the programme. For example, if, as projected, the first list of priority products contains 5 products and each of these is marketed in California by 10 responsible entities, DTSC would have to deal with 50 product notifications (a certain % of which might require follow-up), up to 50 preliminary AA reports (again a certain % of which might require follow-up actions), and up to 50 final AA reports, each probably containing several hundred pages and complex information, many being different from each other in terms of content and quality, all to be analysed by DTSC within 60 days and, if necessary followed-up with complementary submissions by the responsible entities concerned. In parallel, DTSC will have to continue the (also rather demanding) work of identifying further priority products and chemicals of concern and many other activities.

The EU would like to ask whether DTSC has considered an alternative way of crafting the process, which would avoid duplicative work for both responsible entities and DTSC and correspond more to the Restrictions Title under REACH or the Canadian Chemicals Management Plan. For example, after designating a priority product and its chemical(s) of concern and thus requiring responsible entities to notify the priority products, DTSC could then call for submission of all relevant data by a certain date from these responsible entities and all other stakeholders (including the NGO Community) and itself conduct the alternative analysis (either in house, with the help of the Green Ribbon Science Panel, or an outside assessor – in the latter case, costs could be split among all responsible entities having been identified with the priority product notification process according to their turnover with the priority product), and then determine directly a regulatory response. This could well be more efficient in terms of resources required and the necessary time for implementation and would ensure equal treatment of all responsible entities. In fact, in order to be able to review AA prepared by responsible entities and decide on their being appropriate (as required by section § 69505.6) DTSC will in any case need the expertise required for conducting AA and by having to conduct and review multiple AA for the same (or similar) priority product(s) with potentially different outcomes for each of them, the overall workload is multiplied compared to one single analysis. Such an alternative has, unfortunately, not been evaluated under section D of the Economic and Fiscal Impact Statement, where the alternatives considered are all based on the concept that the AA has to be conducted by responsible entities, while nothing in Assembly Bill 1879 on which this draft Regulation is based actually so requires.

² Further information is available at:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

3. Furthermore, the EU would like to elaborate below on the provisions of the draft Regulation related to the accreditation and certification system, with respect to which it has concerns about their compatibility with Article 5.1.1 and Article 5.1.2 of the TBT Agreement.

Article 8 of the draft Regulation establishes a very specific and highly challenging system for the recognition of accreditation bodies who in turn can certify assessors according to very demanding criteria. This creates a serious risk of disadvantaging potential accreditation bodies and potential assessors not located in California. The required qualifications for accreditation bodies cover such a broad range of topics, while also being highly specific, that probably only a university can fulfil them (e.g. extensive experience in teaching and the need to present entire curricula when applying for accreditation combined with knowledge of Federal and State regulatory and statutory requirements for various areas etc.). In addition, the requirements for assessors to become (and remain) certified are very strict and the time frame for DTSC to designate accreditation bodies and for assessors to pass the necessary training and certification process is short. The EU would be interested to know on which basis DTSC has determined that there will be enough certified assessors to conduct all AA as of 2016 – the study underpinning the Economic and Fiscal Impact Statement mentions on page 15 that there could well be a shortage of certified assessors leading to high fees for responsible entities and then claims – albeit without much evidence – that in the long run, firms and individuals seeking profits will attain the accreditation necessary to perform alternative analysis. However, there is no information related to the costs that an interested assessor may face in order to obtain certification, which depending on the amount involved could be a strong deterrent to seek certification.

In this context, the EU would also like to recall that the delegation of the United States to the WTO circulated on 12 March 2012 a Communication on the use of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) by Central Government Bodies, which stated that on 12 January 2012, three White House agencies – the Office of Information and Regulatory Affairs, the Office of Science and Technology Policy and the Office of the U.S. Trade Representative – issued a memorandum for the heads of Executive Departments and Agencies entitled "*Principles for Federal Engagement in Standards Activities to Address National Priorities*", which, among other things contained guidance aimed to strengthen implementation of Article 9 of the TBT Agreement:

"Agencies should evaluate whether their objectives necessitate creating government-unique conformity assessment schemes, which may be expensive to develop and maintain, may impose additional costs on the private sector, and may not be recognized beyond national boundaries. In doing so, agencies should use existing best practices and leverage available resources in the private sector as well as within the Federal Government³."

³ <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf>

Article 8 of the draft Regulation seems to run counter to this US Policy, by setting up a highly unique accreditation and certification scheme that is not recognised beyond State boundaries.

Specific comments:

In the following, the EU will comment on the various sections of the draft Regulation in their order of appearance in the draft text.

Article 1:

§ 69501.1. Definitions

Page 6, lines 10-16: It seems highly unlikely that a chemical substance could have the adverse impacts mentioned under points (A) or (B), and (D) could only materialise if the chemical was intentionally used for that purpose (e.g. asphalt or concrete).

Page 8, lines 10 to 17: The definition of "chemical" is rather specific and not in line with international standards such as "substance" and 'mixture' defined in the UN Globally Harmonised System (GHS). This can lead to confusion and clarity could be increased by specifying that a chemical is either a substance or a mixture and then using the definitions of the UN GHS for these two terms.

Page 8, lines 18 to 21: The definition for the term "molecular identity" is somewhat confusing and includes parameters that go well beyond molecular characteristics. It might be better to use the term 'substance identity'.

Page 10, lines 11 to 14: It is unclear why the term "import" also includes imports into the rest of the United States. It might well be that manufacturers in third countries do not import into California and the Regulation would, therefore, not be applicable to them (or their importers). It should be clarified that the Regulation only applies to products actually placed on the market in California.

Page 13, lines 9 to 10: The final part of the definition of a "retailer" is somewhat confusing. According to the Health and Safety Code in California, the term 'Consumer Product' includes also products sold to professional users. A retailer selling such a product to professionals would, therefore, also be covered by the rules of the Regulation, whilst this definition seems to suggest that this is not actually the case.

§ 69501.3. Information Submission and Retention Requirements

Page 17, lines 5 to 6: When and where will the "manner and electronic format" for data submission be specified? Will DTSC consider using internationally recognised formats such as International Uniform Chemical Information Database (IUCLID)?

§ 69501.4. Chemical and Product Information

As already commented above, the provisions of this paragraph lead to potentially discriminatory treatment between responsible entities solely due to whether they are known to DTSC and receive requests for input or not. An arbitrary selection of

economic operators for soliciting information would create obligations for some but not for others. The EU would like to seek clarification on whether this provision includes also manufacturers in third countries and how DTSC will ensure that they have the same possibilities to act as manufacturers in the US, given that they might not be aware of the obligations under the Regulation and correspondence/communication might not be as easy as with manufacturers based in California (or in the US). In addition, the public listing of companies for having failed to respond to requests from DTSC for information even before a decision has been taken on whether or not a product and/or chemical of concern will be selected for prioritisation is not justified. Rather than contacting individual companies with information requests and denouncing companies for not having submitted information at this stage of the process, DTSC might wish to limit the information requests to general calls as specified in subsection (b)(2) and then publish the names of those companies that have co-operated and responded. This would then be a reward and incentive for companies to participate in line with what is already foreseen in section (d).

Page 18, lines 34 to 35: How will the quality and integrity of voluntary AA be evaluated? Whilst a detailed process is laid out in § 6505.2 to 5 for responsible entities to conduct a "mandatory" AA and in §69505.6 for DTSC to verify the results of a "mandatory" AA, there seems to be no such verification for voluntary AA.

§ 69501.5. Availability of Information on the Department's Website

This paragraph sets out a long list of information to be made available on DTSC's website, much of which will require almost constant updating. As this will be very resource-intensive and bears a high risk of displaying inaccurate information, DTSC might wish to consider prioritisation of a more selected list of information for publication. Has DTSC ensured that the publication of the names of individual persons (e.g. as required by subsection (b)(3)(D) the person that will fulfil the requirements of article 5) is compatible with rules on the protection of personal data?

§ 69502.2. Chemicals of Concern Identification

Page 21, lines 30 to 32. The EU supports that the draft Regulation refers to substances classified in the EU and also to other recognised classifications. As an editorial remark, the EU would suggest that the correct wording of the reference in point (B) should rather be as follows:

"(B) Chemicals classified as carcinogens, mutagens and/or reproductive toxicants Categories 1A or 1B in Annex VI to Regulation (EC) No 1272/2008"

The EU notes that the legal certainty for references to lists of endocrine disruptors and persistent, bioaccumulative and toxic substances as indicated in points (C) and (G) could be improved by reference to those that have been officially identified for these characteristics in accordance with the procedure outlined in Article 59 of REACH:

"(C) Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH as endocrine disruptors⁴.

.....

⁴ The list is available at: <http://echa.europa.eu/candidate-list-table>

(G) *Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH for being persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative."*

§ 69503.4. Priority Products List

Page 29, line 35: Why has a criterion of more than 100 manufactured components been selected to identify a 'highly durable product'? There can be many highly durable goods with less than 100 components, for example furniture, mattresses, carpets etc.

Page 30, lines 3 to 4: A reference to products that are '*dispersed as an aerosol or vapour, or applied to hard surfaces with the likelihood of runoff or volatilization*' in the context of highly durable goods seems misplaced. By their very nature, these products cannot be highly durable goods.

Page 30, lines 35 to 38: How will priority products be identified in the list? By (more) general descriptors of purpose and function, or by individual brand names? It could be very important for companies to know this in order to assess whether their products are concerned or not. Also, can DTSC provide an estimate of how many chemicals of concern will be identified in the initial list as the reason for listing the (up to five) priority products?

§ 69503.7. Priority Product Notifications

The EU would be interested to learn how DTSC will ensure that all responsible entities concerned will comply with their obligations under this paragraph, which is also the basis for all subsequent obligations. Point (b) sets out the consequences of a failure to comply, but does not describe any steps that DTSC will take in order to determine cases of non-compliance. This is not set out in the draft Regulation, nor in the Initial Statement of Reasons.

Article 5. Alternatives Analysis

As already pointed out above, the requirements in the draft Regulation for conducting alternatives analysis (AA) are highly complex, both technically/content-wise and administratively with multiple notifications and submissions of reports, each of which will require reactions by DTSC and the submitting entities. The time periods foreseen for completing the various steps seem short compared to the tasks to be accomplished, in particular for preparing a final AA report (12 months) and for DTSC to review and react to the final report (60 days). For reasons of comparison, the EU would like to inform the US authorities that under REACH the normal time frame for preparing a request for authorisation for continued use of a substance on Annex XIV of REACH (which includes an analysis to demonstrate that there is no suitable alternative for the substance concerned) is between 18 and 24 months (while the range of parameters to be analysed is substantially narrower than in the draft Regulation of California), whilst the European Chemicals Agency (ECHA) has then one year to provide the opinions of its Risk Assessment Committee and its Socio-Economic Analysis Committee, before the Commission takes a formal decision on whether or not an authorisation for continued use of a substance can be granted.

Page 36, lines 4-7: The EU observes that it will be absolutely indispensable that California develops guidance for the implementation of the very demanding obligations that companies have to comply with under the draft Regulation. In particular for small and medium size companies it will be extremely difficult to conduct the required alternative analyses – even with guidance. Third country authorities and trade associations should be involved in the process for the development of such guidance documents. The EU also offers to make available the very extensive guidance that has been developed for the purposes of REACH and CLP, which could be a good starting point for the authorities in California.

Page 37, line 39-40: This provision specifies that *'Failure of the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request'*. However, what does this mean for a responsible entity having submitted a request without response within 30 days? It would need to know according to which timeline it has to prepare the AA.

Page 37, line 42 to Page 38, line 1: The draft Regulation requires that all AA completed on and after the date that is two years after the date on which the Regulation takes effect have to be conducted by assessors certified for the appropriate product type and industry sector. However, against the background of the very demanding process for obtaining certification (see comments above on Article 8), what evidence does DTSC have that there will be enough certified assessors available by that date and that their services can be procured at reasonable costs?

Page 38, lines 6 to 10: As already commented above, the provision to allow a responsible entity to fulfil its requirements to conduct an alternative analysis (AA) by submitting to DTSC a report for a previously completed AA for the Priority Product is problematic. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection) as otherwise the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

Page 39, lines 4-5: it seems excessive to require that responsible entities must summarise in their AA reports how they have made use of information made available on DTSC's website.

Page 34, lines 6-10: as already commented before, and for reasons of legal certainty, the Regulation should specify the consequences of DTSC's failure to react within the required deadline rather than specifying what this failure does not mean.

Page 40, lines 25 to 32: The provisions in this subsection are somewhat confusing as they seem to allow the placing on the market in California of new priority product(s) containing chemical(s) of concern (subject to the conduct of an AA within a certain deadline), even after the products have been listed, all responsible entities having already conducted their AA and DTSC having already imposed a regulatory response (which might actually be a ban or an obligation to replace a chemical of concern). This provision should, therefore, be limited until such time that DTSC has imposed a regulatory response for a given priority product after which any entity wishing to

market a new product would have to comply with the regulatory response. It seems not efficient to require another AA to be conducted then.

Page 42, line 31 to page 45, line 15: The EU would comment that the range of factors to be analysed during the second step of the AA is extremely broad, which makes it very difficult to conduct the analyses within reasonable cost and time. For many parameters it will be virtually impossible to find (or just model) the required data, and this will be even more complicated if products are manufactured in third countries. The EU notes that in the framework of the Economic and Fiscal Impact Statement DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate. The EU would also like to recall that in the development of the REACH Regulation, the Commission, the Member States and industry conducted numerous feasibility experiments – the so called Strategic Partnership on Reach Testing (SPORT) and Piloting REACH for Downstream Use and Communication in Europe (PRODUCE)⁵, the results of which led to significant changes between initial drafts and the final Regulation in the light of feasibility and proportionality considerations.

Page 46, lines 32 to 34: There is no particular reason to require this information as part of the AA as it does not bring any meaningful contribution to the analysis. In fact, the chemical industry and the broader manufacturing industries are operating globally. Even if a particular chemical is produced very close to a plant consuming this chemical in the manufacturing process of a product, that chemical (or an alternative) can easily be sourced from another country. It is also not clear what consequences this requirement would have for products manufactured in third countries.

Page 48, lines 10 to 11: It is unclear how a responsible entity could comply with this obligation. If certain information is not available, it is difficult to assess whether it would meet the criteria listed under points (A) to (C).

Page 48, line 34 to Page 49, line 22: This subsection establishes the obligation to determine the entire chemical composition of a selected alternative product. It will be extremely difficult in the case of complex products such as cars or household appliances to conduct an assessment of the entire chemical composition of each component in their product, as these are often assembled out of hundreds of different components, each containing potentially many different chemicals and provided by a variety of suppliers possibly in different countries. If DTSC maintains this requirement, it actually creates a strong incentive for responsible entities not to select an alternative and maintain the priority product as then they do not seem to have to comply with this obligation. A more feasible approach would be to limit the information requirement to whether the selected alternative contains other chemicals of concern.

Page 51, lines 1 to 10: as already commented before, the time frame for DTSC to review an AA report (60 days) and also the time frame for responsible entities to redress deficiencies (60 days) seem excessively short against the background of the complexity of the work required.

⁵ Further information is available at:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

Article 6. Regulatory Responses

As a general question, what will DTSC do in the case of diverging or conflicting results of alternative assessment for the same/similar products and chemical(s) of concern? Given that many different actors will conduct AAs the risk that there will be diverging results with regard to regulatory responses will be quite high. Does § 69506.1 have to be understood in the sense that DTSC will ultimately impose the same regulatory response on all responsible entities or will there be different ones for different entities?

Page 53, lines 29 to 39: § 69506.2 entails again a significant risk of discriminatory treatment between responsible entities. If requests for additional information are made, they should concern all entities and not only individual ones. If one of them has already provided the information, DTSC could increase efficiency by using it and require all others to participate in the costs of the first one for generating the information, rather than requiring them to produce the same information again.

Page 54, lines 23 to 24: Is the intention really to require the listing of all chemicals of concern or rather the chemicals of concern due to which the product had been identified as a priority product? In fact, lines 34 – 35 specifically refer to the applicable alternatives analysis thresholds, which only exist for the chemicals of concern due to which the priority product had been selected.

Page 55, line 29 to page 57, line 5: It is not clear why DTSC wishes to operate with individual notifications to responsible entities to establish product sales prohibitions. Would it not be more efficient and less discriminatory, if, instead, DTSC established a horizontal rule prohibiting the product (or chemical of concern) in general and for all entities wishing to place it on the market in California?

Page 57, line 29 to page 59, line 17: The regulatory response to set up a comprehensive end-of-life management programme (including comprehensive financial guarantees and burdensome yearly reporting) seems impossible to meet for individual companies – in particular for manufacturers that are SMEs and/or located in third countries - and can probably only be achieved if the DTSC establishes a rule applicable to (a range of) products that would apply to all responsible entities to create this jointly. Again, the EU would like to know whether the DTSC has undertaken any feasibility studies with regard to this particular regulatory response, in particular for SMEs. In the light of the high costs involved, this regulatory response could amount to a disguised ban on marketing the product in California.

Page 59, lines 22 to 59: The EU would like to know according to which criteria the obligation to fund 'Green Chemistry' Research will be put into practice. How will the amounts be determined that a responsible entity will have to provide? As a share/percentage of overall sales? How will the DTSC avoid discriminatory treatment of different responsible entities?

Page 61, lines 18 to 24: Again, this subsection implies that different responsible entities will get different regulatory responses imposed for the same (or similar) priority product(s). It would seem more logical that DTSC informs all retailers and publishes general rules about one identical regulatory response applicable to all responsible entities in a non-discriminatory way.

Page 61, line 37 to page 62, line 22: these subsections establish burdensome reporting requirements for responsible entities and even more so for DTSC itself, as the number of products and regulatory responses concerned could easily run into the hundreds after a few years and would grow continuously over time.

Article 8: Accreditation Bodies and Certified Assessors

See comment number 3 in the section on general comments above.

The EU thanks the US authorities in advance for taking into account the above comments and looks forward receiving a reply.



RON CHAPMAN, MD, MPH
Director & State Health Officer

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

October 8, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safe Consumer Product Alternatives Regulations (R-2011-02)

Dear Ms. Von Burg:

The California Department of Public Health (CDPH) is writing to express its general support of the Department of Toxic Substances Control's (DTSC) Safe Consumer Product Alternatives regulations (Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04). As an organization dedicated to optimizing the health and well-being of the people in California, CDPH promotes and supports policy decisions that are likely to result in the improved health of all Californians. We feel these regulations, if adopted and implemented as written, will be a valuable shift in approach to evaluating the safety of consumer products and to promoting the formulation of new products without chemicals that cause cancer and other adverse health effects.

Consumer products that contain hazardous chemicals also may be used in the workplace and therefore place both consumers and workers at increased risk for negative health effects. Additionally, the manufacture of these products may place workers at risk of exposure to toxic materials during the manufacturing process. CDPH has responsibilities and authorities for regulating some consumer products, monitoring the health of populations and for assessing conditions and hazards in the workplace. We appreciate DTSC's recognition of these roles and responsibilities and our inclusion in the processes of drafting and implementing these regulations.

We have some concern that the regulations as written overlap or duplicate CDPH's responsibilities and efforts to regulate certain consumer products under the Health and Safety Code (HSC). Specifically, HSC 25257.1 (a), (b), and (c) restrain DTSC from overlapping or duplicating other state and federal agency jurisdiction and regulatory authority. We propose working together to ensure appropriate language be included in the final adopted text of the regulations to avoid duplicating regulatory authority.

We suggest a Memorandum of Understanding that covers identifying priority products, sharing data and resources between the two departments and clarifying specific language or procedures for avoiding duplication of effort may be a useful mechanism to formalize our collaboration.

We appreciate the effort DTSC has expended to draft these complicated regulations and we look forward to working together in the future to evaluate and improve the safety of consumer products sold in California with the goal to improve the overall health of Californians as well as to protect the environment.

Sincerely,

A handwritten signature in black ink, appearing to read "Ron Chapman".

Ron Chapman, MD, MPH
Director and State Health Officer
California Department of Public Health

**COMMENTS ON THE
CALIFORNIA SAFER CONSUMER PRODUCTS
DRAFT REGULATIONS OF JULY 27, 2012**

October 11, 2012

**CHANGE Coalition
Californians for a Healthy and Green Economy**

Californians for a Healthy and Green Economy (CHANGE) offers the following comments on DTSC's draft regulations to implement a Safer Consumer Products program under the authority of AB 1879. CHANGE is a statewide coalition of environmental and environmental justice groups, health organizations, labor advocates, community-based groups, parent organizations, faith groups, and others who are concerned with the impacts of toxic chemicals on human health and the environment.

We have closely tracked the development of the regulations by DTSC from the beginning. We appreciate that DTSC has provided CHANGE with the opportunity to provide the public interest perspective of our member organizations on this important effort.

Please let me know if you have any questions about these comments.

Sincerely,



Kathryn Alcántar
CHANGE Campaign Director

CHANGE acknowledges that this is the first time a regulatory agency has set out to build a broad chemicals regulatory structure that has been mandated by statute to require analysis of alternatives to toxic chemicals. This is the first time an agency has attempted to regulate chemicals, and the products that contain them, by focusing first on intrinsic hazard traits of chemicals rather than exclusively relying on risk assessment. This is the first time chemical regulations are attempting to incorporate cumulative exposures, which are a key public health concern and as well as a long-standing demand from environmental justice communities. And this is the first time manufacturers of consumer products will be required to formally answer the question, “Is the use of this hazardous chemical necessary in my product?”

This approach constitutes a long-overdue paradigm shift in how society should manage chemicals, and represents an effort to generate a process of continuous movement towards a green economy, in which toxic chemicals can be replaced with non-toxic alternatives. Such an approach focuses on public, occupational, and environmental health, maintaining the essential concept of primary prevention.

Two components of the draft proposal are essential in our view and must be retained. The first is a large Chemicals of Concern (CoC) list that is unranked. The second is the requirement that the Department set science-based, case-by-case alternative analysis threshold levels. Detailed comments about these two issues are below.

However, as we have observed before, some portions of the draft regulations contain deep flaws that need to be fixed. In particular, there are two critical aspects to the program that require improvement: the standard of causation DTSC is requiring of itself to consider action; and the lack of transparency and oversight in the generation of Alternative Assessment reports. Our detailed comments about these issues also appear below.

Beyond these content issues, funding must be found so DTSC can carry out the program. There is consensus among all stakeholders that DTSC does not have the resources to undertake implementation in a sustained way. DTSC has said that only 2-5 product categories will be identified in the first round, and a final alternative analysis report will take three years if all goes smoothly. The pace of work outlined in the draft regulations will lead to very modest accomplishments. It would be impossible to argue that the program can generate any significant throughput without additional funding.

Providing DTSC with the means to implement this program should be a top priority for the Legislature. CHANGE intends to continue to communicate this priority to elected officials. However, as a first step, we urge DTSC to build permitting and licensing fees, which would not rely on legislative action, into the regulations.

Furthermore, a “no data, no market” requirement must be developed to close the pervasive data gaps about chemical information and to put all chemicals, both new and old, on a level playing field. DTSC’s limited ability to create a requirement for a minimum data set for all chemicals in commerce under its existing authority is a critical shortcoming of the proposed program. Building a “no data, no market” mechanism into California’s regulatory structure is a big job that remains to be undertaken. This is another key task for the Legislature: filling the data gaps outlined in the 2006 report “*Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*” which was commissioned by the Legislature in 2004.

CHANGE’s view of the draft regulations is that there are important improvements that still need to be made so they can be as effective as possible. But it is now time for DTSC to quickly bring this program online and see how it works in the real world.

A comprehensive Chemicals of Concern list is critical to the SCP program's success.

CHANGE strongly supports DTSC's plan to post a robust list of Chemicals of Concern (CoC) within 30 days of the effective date of the regulations that relies on the work of authoritative science bodies. The proposed list contains chemicals for which there is already sufficient cause for concern for human and environmental health. Relying on authoritative bodies, which have listed chemicals after comprehensive and peer-reviewed scientific processes, constitutes a thoughtful and reasonable process for the identification and prioritization of Chemicals of Concern.

The language of AB 1879 explicitly requires DTSC to identify chemicals of concern in Section 25252 (a). There is no mention in the statute of a category called "chemicals under consideration" and therefore CHANGE believes retaining the term "chemicals of concern" in the regulations is appropriate and legally required.

A large CoC list will support, encourage, and stimulate efforts by forward-thinking entrepreneurs and businesses to voluntarily act before subsequent regulation compels them to do so. This will create jobs for California's green economic development. The size of this list will, as DTSC intends, help reduce the problem of regrettable substitutions. A large CoC list will enable DTSC to use scarce resources for other important program activities.

While some may claim that the estimated 1,200 chemicals which will be listed is too large a number to be meaningful, in fact it represents only a small fraction of the more than 80,000 industrial chemicals currently registered for use in the U.S., most of which are not adequately tested for health and safety effects before reaching the market.

CHANGE also strongly supports DTSC's intent not to rank chemicals on the CoC list in what would be a misguided effort to identify and prioritize the "worst" chemicals. We believe such an effort is inherently impossible because of the pervasive data gaps and difficult judgments that would be required to compare and rank different kinds of harm. It would result in an endless paralysis by analysis and lead to fruitless litigation over the resulting prioritization. Moreover, such ranking is not required by AB 1879. An unranked list is consistent with the approach used by other states with similar programs. Chemicals on the list have made it through prioritization processes of a variety of reputable scientific bodies and legislative authorities. An unranked list also provides strong market signals so that manufacturers and others can begin looking for alternatives before products are prioritized.

DTSC should specify that when any lists it relies on are updated, the updated list becomes the version that DTSC uses in its own CoC list.

We support the addition of the Priority Chemicals list of the California Environmental Contaminant Biomonitoring Program.

The proposed CoC list needs some additions. DTSC should ensure that all hazard traits identified by OEHHA are captured in its CoC list, including neuro-developmental hazard traits.

DTSC should also augment the list with substances of particular relevance to workers and consumers: asthmagens, respiratory sensitizers, skin irritants/sensitizers. OEHHA lists these hazard traits already (e.g., Chapter 54, s. 69403.16 Respiratory Toxicity) and there are lists available from North America and Europe. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) also includes these

hazard traits, which the US federal *Hazard Communication Standard* will require to be considered on “safety data sheets” in the next few years. California already plans to follow suit, adopting the federal changes at a minimum.

For asthmagens and other sensitizers:

- <http://www.cdc.gov/niosh/topics/skin> (NIOSH information about skin irritants and sensitizers);
- <http://www.aoecdata.org/ExpCodeLookup.aspx> (Association of Occupational and Environmental Clinics -- AOEC);
- <http://esis.jrc.ec.europa.eu/index.php?PGM=cla> (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
- http://www.cleanproduction.org/library/greenScreenv1-2/Green_Screen_v1-2_Supporting_Lists.pdf

Other lists CHANGE recommends including are the following:

- Washington State Department of Ecology *Reporting List of Chemicals of High Concern to Children* at <http://www.ecy.wa.gov/programs/swfa/cspa/chcc.html>;
- Minnesota's list of 1,700 chemicals of high concern in 2010 under the *Minnesota Toxic Free Kids Act*;
- Maine's list of 1,700 chemicals of high concern in 2009 under the Maine Toxic Chemicals in Children's Products Law;
- California's 303(d) list of impaired waterways: http://www.waterboards.ca.gov/water_issues/programs/tmdl/303d_lists2006_epa.shtml.
- The Skin Disease portion of the Haz-Map database from the U.S. National Library of Medicine, <http://hazmap.nlm.nih.gov/types-of-diseases>; and
- The Green Chemistry & Commerce Council's *an analysis of corporate restricted substance lists (RSLs) and their implications for green chemistry and design for environment*, November 2008 (chemicals listed in Appendix 1), <http://www.greenchemistryandcommerce.org/publications.php>

We are alarmed that the proposed list of CoCs does not include the 303(d) list of the federal Clean Water Act for contaminants impacting California waterways. This is the central list by which to identify water pollutants impairing the state's waters to the degree that they violate water quality standards as specified by the federal Clean Water Act and California's Porter Cologne. It is necessary to include the contaminants on the 303(d) list in order to ensure that water quality is given the priority it deserves when identifying CoC/Priority Product combinations. Without it, we do not see a pathway for DTSC to address water quality concerns. Furthermore, the regulations should indicate that Department will review the list each time it is updated by the California State Water Resources Control Board.

§ 69502.2(b)

In addition, it is important to provide a mechanism for additions to the CoC list that do not appear on existing authoritative body lists. New peer-reviewed science, for example, can point to health or environmental concerns before authoritative bodies can act. As written in the current draft, CHANGE supports DTSC having the authority to identify new CoCs based on their hazard traits or environmental or toxicological endpoints. This is an important avenue for new chemicals of concern to be identified as soon as possible, and it further distinguishes the Safer Consumer Products program as forward-looking.

§ 69504.(a)

CHANGE supports the petition process whereby a person may petition DTSC to add or remove a chemical or the entirety of an existing chemical list to the SCP CoC list.

§ 69502.3(a)

DTSC needs to specify how often the CoC list will be formally updated. As currently written, DTSC will do

this "periodically." CHANGE urges that the CoC list be updated at least every two years.

§ 69502.3(c)

CHANGE supports the opportunity for formal public input on proposed revisions to the CoC list.

CHANGE strongly supports the removal of default alternative analysis (*de minimis*) threshold exemptions.

One of the most important improvements in the new proposed regulations is the removal of the alternative analysis threshold (AAT), or what was termed a "*de minimis*" level in previous drafts. CHANGE, along with many from the scientific community, members of the Green Ribbon Science Panel, a coalition of 44 wastewater agencies, and many other environmental and public health groups pointed out the serious problems inherent within the proposed default alternative analysis threshold. We are gratified to see that DTSC has addressed these serious concerns and eliminated default AAT thresholds from the proposed regulations.

While we recognize that the previously proposed default thresholds of 0.01 percent and 0.1 percent (depending on the health endpoint in question) was somewhat more protective than *de minimis* thresholds in other programs and was an improvement over the original proposed 0.1 percent threshold for all health endpoints, these default thresholds nevertheless lacked scientific justification and would have posed significant public health hazards.

For example, a consumer product could have contained 20 times more lead or arsenic, 100 times more cadmium, 200 times more benzene, and 500 times more mercury than what would be considered a hazardous waste under federal Environmental Protection Agency regulations, but be exempted *a priori* from undergoing alternative analysis under DTSC's previous proposed regulations. Given that DTSC is the California agency that enforces EPA hazardous waste regulations, this provision of the regulations was simply unsupportable.

We also know from peer-reviewed research that some chemicals, previously thought to be harmless, can in fact have adverse impacts at extremely low doses. For the endocrine disruptor bisphenol A, for instance, effects can be observed in the parts-per-trillion range. A threshold of 0.01 percent would have failed to be protective by several orders of magnitude. Endocrine disruptors in general would have been under-recognized within DTSC's proposed structure.

Moreover, the previously proposed AAT exemption would have created perverse incentives that ran counter to the intent of the program. For example, product manufacturers would have been motivated to continue to use chemicals of concern (and other dangerous chemicals) as long as they were below the AAT threshold. Manufacturers would also have been motivated to replace a chemical of concern used at levels above the threshold with multiple chemicals of concern each at levels below the threshold. These counter-productive incentives would have undermined the intent and central goal of AB 1879, to prompt a search for safer alternatives.

We commend DTSC for its decision to affirm scientific integrity and chemical-specific alternative analysis thresholds for each product category the agency prioritizes for review. This approach is vastly preferable to a one-size-fits-all approach that lacks scientific integrity and undermines the intent of the Safer Consumer Products program.

Illegal standard of causation language

The proposed regulations employ a burden of proof for causation that is higher than that specified by AB 1879. That burden should be conformed to the requirements of AB 1879.

We believe that DTSC has strayed so far from the clear provisions of AB 1879, the intent of the law and the Green Chemistry Initiative and the earlier drafts of the regulations that we request that DTSC provide a full written explanation of its decision on this issue, including answers to the six questions we pose below, at the end of this section.

This erroneous causation standard carries enormous consequences for the program. It will in practice disable the program from its goal of encouraging industry and society to begin to avoid early warnings of harm. It also causes the regulations to diverge from DTSC's goal of making them legally defensible. This destabilizes the program because not only may NGO's legal challenge the validity of the regulations, but one can expect an individual industry to do so as well whenever DTSC attempts to enforce the regulations or a regulatory response against that industry. Moreover, the erroneous causation standard destabilizes the initial COC list by potentially opening an avenue for removing chemicals from that list. For all of these reasons, we hope DTSC will take this issue very seriously.

AB 1879 explicitly requires DTSC to establish a process for identification of chemicals of concern that must include evaluation of the "potential" effects of a chemical on sensitive subpopulations, including infants and children, HSC § 25252 (a)(3), and evaluation of the "potential" for exposure to the chemical in a consumer product, HSC § 25252(a)(2). It requires DTSC to develop a process for evaluating alternatives to a COC that must include evaluation of all the "potential" hazards of the alternatives. HSC § 25253(a)(2); 25253 (a)(2)(K). Finally, AB 1879 instructs DTSC "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern" in fashioning a regulatory response after the alternatives assessment process is complete. HSC §25253(a)(1). The requirement for DTSC to determine how best to limit exposure or reduce the level of hazard is consistent with the concept of reducing even potential exposures and hazards wherever reasonably possible.

Thus, AB 1879 requires DTSC to develop a process to evaluate the "potential" hazards of and "potential" exposures to chemicals when identifying them as COCs, and then a process to evaluate the "potential" hazards of any potential alternatives before DTSC may then fashion a regulatory response to best limit exposure or reduce the level of hazard.

In contrast to these unambiguous requirements of AB 1879, the objective of the current regulatory proposal is to evaluate and respond only to hazards that a chemical is shown to have the "ability" to cause or contribute to. The "potential" standard of earlier draft regulations has been replaced by the "ability" standard virtually throughout this version. As one example, §69502.2(H)(b)(1)(A) provides that in order to list a chemical as a chemical of concern, DTSC must consider the "ability of the chemical to contribute to or cause adverse public health and/or environmental effects." (This and similar standards of causation used at various places in the proposed regulations that recite or imply the word "ability" are referred to herein as "ability" standards of causation.) "Ability" rather than "potential" is now used in the provisions relating to whether a chemical can be identified as a COC (see, for example, p. 23, line 12; p. 23, line 23; p. 23, line 34; p. 23, line 40). It is used in the provisions relating to identification of a priority product (see, for example, p. 25, line 32; p. 26, line 2; p. 26, line 5; p. 26, line 17; p. 27, line 9; p. 27, line 27; p. 27, line 27). It is used or implied in the provisions relating to preparation of an alternatives analysis (see, for example, p. 42, lines 3-7; p. 42, lines 14-16; p. 43, lines 8-12). It is similarly implied in the very definition of a safer alternative (see p. 13, line 14). It is explicitly used in

some of the provisions relating to regulatory responses (see, for example, p. 55, line 13; p. 55, line 38) and effectively by implication in others (see, for example, p. 52, line 8; p. 52, line 12; p. 54, line 5).

In the paragraph above we have sometimes said that a provision uses the “ability” standard by implication. Let us explain that. Take, as an example, the regulatory response section §69506(a). That section provides that DTSC shall implement regulatory responses designed to protect public health and the environment and maximize use of alternatives of least concern. There is no explicit reference to the term “ability” (or “potential” or any other particular standard) in that section. But, if COC’s and alternatives are identified and compared in AA’s that consider solely evidence that meets the “ability” test, with any lesser evidence showing only “potential” adverse effects discarded from the analysis, then any regulatory response by DTSC could only protect public health from adverse effects from COC’s or alternatives that can be shown to meet the “ability” test. DTSC will not be able to protect the public or environment from “potential” hazards because DTSC will have no evidence of any such potential hazards in the record for it to consider. Similarly, in maximizing use of alternatives of least concern, the only evidence DTSC will have before it in AA Reports will be any evidence that the COC and alternatives meet the “ability” test, with all lesser evidence of potential harm removed from its consideration. Thus, the “ability” test is impliedly employed in this section.

The same issue arises in §69506(b), which instructs DTSC to focus on “avoidance or reduction of adverse impact or exposure” by a COC in a product. Again, the section does not explicitly recite the “ability” test. But the only evidence of any adverse impact or exposure that will be present in the AA Report being considered by DTSC will be that rising to the level of meeting the “ability” test. Evidence not rising to that level will not be part of the record for DTSC to consider. Again, the “ability” test is impliedly employed in this section.

While the proposed regulations use the “ability” test explicitly in numerous places, the impact of that test is felt even more broadly and, indeed, infects every aspect of the proposed regulations. The pervasive use of the “ability” standard explicitly and by implication means that potential hazards cannot be considered by DTSC in identifying COCs, by alternatives assessors comparing alternatives to COC’s, or ultimately by DTSC in fashioning a regulatory response. This approach, which contrasts with that mandated by AB 1879, would not fulfill the requirements of the law.

The bottom line: the use of the “ability” standard of causation in the proposed regulations is illegal under AB 1879.

One potential contradiction in the proposed regulations in particular should concern DTSC. That is that many of the authoritative bodies relied on for identification of the initial COC list very likely use a standard that is less stringent than the “ability” test of these proposed regulations. Does use of the “ability” standard in the regulations undermine DTSC’s ability to rely on those authoritative bodies? Will it be used by industry to have COC’s removed from the initial COC list where the evidence used by an authoritative body does not rise to the level of the “ability” test? How can DTSC justify these contradictions?

There is an enormous difference between a chemical that presents a “potential” hazard and one that has the “ability” to contribute to cause an adverse effect. The scientific reality of the impact of toxic chemicals on the environment and human health is that often the best evidence available is that a chemical may contribute, along with other chemicals and other environmental factors, to adverse effects on human health and the environment. The difference between the standards is that between acting on early warnings of harm and waiting for proof of harm before acting. The former is the goal of all modern chemical policy reform efforts, including the Green Chemistry Initiative. The latter represents the discredited approach urged and sought by the chemicals industry as it seeks to externalize the damage from its chemicals onto society. As compared to a “potential” standard,

because it would remove early warnings of harm from consideration under the regulations, the “ability” standard disables DSTC from acting on early warnings of harm and therefore is essentially deregulatory in effect.

There was a time in the not too distant past when DTSC clearly understood this issue and the requirements of the law. Draft proposed regulations as recent as the October 31, 2011 version, after 3 years of drafts and regulatory development, were directed to “potential” adverse effects. It is only recently under the Brown administration that DTSC has lost its way on this issue.

We understand there to be several reasons offered for adopting the “ability” standard. One is that the “potential” standard could allegedly be met by any chemical, even those for which there is no data at all. We disagree. Establishing that a chemical has the “potential” to exhibit a hazard trait requires a body of reliable information. In our view, words other than “potential” can carry the same meaning, such as the word “may,” as in the “may present” standard of TSCA Sections 4 and 5. In the case of TSCA, no one has ever suggested that TSCA’s “may present” standard can be satisfied in the complete absence of evidence.

DTSC should be clear that use of the “potential” standard is not the same as switching the burden of proof onto industry (which would mean that chemicals are assumed hazardous until proved otherwise). A complete absence of information cannot establish that a chemical is potentially hazardous. The “potential” standard is a lower, but not a switched, burden of proof.

To remove any confusion about this issue, if that is the problem, we suggest DTSC provide a simple definition of “potential” to exhibit a hazard trait and clarify that any finding of a “potential” hazard requires reliable information to substantiate the finding.

A second reason suggested is that the term “ability” is allegedly “less ambiguous” than the term “potential.” We emphatically disagree. There is nothing inherently more ambiguous about the term “potential” than about any other term defining a burden of proof. Even TSCA contains legal standards such as whether a chemical “may” present an unreasonable risk. See TSCA, Sections 4, 5. Standards such as “may present” or “potential” are not vague as compared to more stringent standards such as “ability” or “beyond a reasonable doubt”; they establish lower burdens of proof but are not more vague. Whatever standard is chosen, whether “ability” or “potential,” there will undoubtedly be disputes over its precise meaning until some content is given to it through experience or a clear definition is provided. But there is nothing inherently more vague about “potential” as compared to “ability.”

Indeed, just the opposite. Substantial confusion has emerged as to exactly what is meant by the “ability” standard. If anything, it is the vaguer term. Does it mean that a chemical must be proved to be able to cause adverse effects under any circumstances, regardless of whether those circumstances exist in the real world (such as through high dose tests)? Or does it mean that a chemical must be shown to be able to cause adverse effects as it is used in practice? In law, this is the distinction between specific and general causation – which is meant by the “ability” standard? DTSC should ask itself and answer the questions: has BPA been shown to have the “ability” to contribute to or cause an adverse effect? Have brominated fire retardants? Has mercury? Is DTSC going to be able to regulate any chemical hazard under this standard?

For all these reasons, CHANGE believes that the “ability” causation standard is illegal under AB 1879, and is also bad policy that flies in the face of the purpose of the California Green Chemistry Initiative. The regulations should be reoriented toward “potential” hazards by pervasive substitution of the “potential” standard for the “ability” standard in at least the places identified above.

In the event that DTSC does not reorient the regulations to the “potential” standard, then CHANGE requests that the Department explain in writing the following:

- a. Why does AB 1879 not require the regulations to employ the “potential” standard?
- b. What standard does AB 1879 authorize and what is the evidence for that?
- c. If the Department insists on adopting the “ability” standard, what is the legal basis for adopting that standard rather than some other standard that would provide more public health protection than the “ability” standard, such as a “reasonable likelihood” standard, “likely” standard or “probable” standard?
- d. If the Department chooses to retain the “ability” standard, what is the policy basis for adopting it, including an explanation of (1) the balance the Department is seeking to strike between protecting public health / environment and vested commercial interests and (2) the reason it must be applied throughout the regulations rather than in some places but not others?
- e. If the Department chooses to retain the “ability” standard, what exactly does it mean? Does it refer to the inherent ability of a chemical to cause an adverse effect, or to proof that the chemical does cause such effects as used in the real world, or to something else?
- f. Do all of the chemicals on the initial COC list all meet the “ability” standard of causation, and if they do not, must they be removed from the COC list; and why or why not?

Minimize regrettable substitutions by prioritizing classes of chemicals.

The draft regulations may result in regrettable substitutions as companies switch out of chemicals of concern before their product is designated as a priority product. Past proposals for implementing regulations have included: (1) a no data, no market requirement for all or most chemicals in commerce; or (2) detailed, admittedly cumbersome reporting requirements anytime a CoC is altered in any product. The current regulations do not address this, although the large number of CoCs may help somewhat with this problem.

Prioritizing classes or groups of chemicals or products, rather than taking them up individually or relying on authoritative body listings, would minimize regrettable substitutions. DTSC should consider building in a mechanism to do this when appropriate.

We suggest that at the very least, DTSC should try to collect information about the extent of this problem to inform the design of future elements of the GCI. In these regulations, DTSC could and should develop regulatory provisions to help accumulate information as to whether and how often companies switch out of CoCs prior to entering the formal AA process. For example, companies could be required to report to DTSC if they switch out or reduce the amount of a CoC in any product once the CoC list is finalized. A simple, non-burdensome program could provide information of great value in the further development of the regulations.

Cumulative exposures/impacts is an important component of the program.

CHANGE strongly supports DTSC's efforts to build in cumulative exposure. Addressing this regulatory challenge is long overdue and is a fundamental concern for many environmental justice communities and public health experts. It is important and appropriate because emerging science shows that many of our environmental and public health problems stem from the cumulative impact of many diverse stressors, often including, but not limited to, numerous chemicals. The European Commission, for example, has recognized that multiple exposures from combinations of chemicals have not been adequately addressed in existing regulatory structures and has taken steps to develop new approaches – see <http://ec.europa.eu/environment/chemicals/effects.htm>.

California EPA is engaged in an ongoing process that is studying cumulative impacts (OEHHA's Cumulative Impacts and Precautionary Approaches Workgroup). As OEHHA continues its work to develop tools to address this, we encourage DTSC to maintain its commitment to this issue.

What is important to consider is the impact of chemicals as they accumulate with other broadly defined environmental factors, not just "other chemicals with the same or similar hazard traits." Therefore, as before, we recommend that the regulations include language that commits DTSC to examining cumulative effects not just with other chemicals but "with other environmental factors" which include, but are not limited to nutrition, the built environment, and socioeconomic status.

We recognize that cumulative impacts are difficult to quantify, and yet it is also important to not restrict the scope of inquiry. Qualitative or semi-quantitative analysis of the real scope of impacts is more likely to be useful than greater quantitative analysis of a small portion of impacts.

§ 69502.2(b)(1)(A)(3) Page 23 line 16

Current language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The chemical's cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors.**

§ 69503.2(a)(1)(A)(1)(c) Page 25 line 38

Current language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints.

Suggested language: The Chemical(s) of Concern cumulative effects with other chemicals with similar hazard trait(s) and/or environmental or toxicological endpoints, **as well as with other environmental factors.**

§ 69503.5 (d) Page 32 line 26

CHANGE strongly supports this section so that if multiple Chemicals of Concern exhibit the same hazard trait and/or environmental or toxicological endpoint(s) that have been identified as the basis for the products being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such CoCs.

Environmental impacts are neglected in the first round selection of Priority Products and should be included.

CHANGE has consistently advocated that environmental endpoints be prioritized along with human health impacts when establishing both a Chemicals of Concern (CoC) list and choosing Priority Products. Our concern has been that environmental issues are often not as readily apparent or seen as urgent as hazard traits such as carcinogenicity or the known ability of a chemical to cause reproductive harm. However, environmental protection is critical for a variety of reasons:

- A healthy environment is essential to the overall well being of society and is in and of itself worthy of protection.
- Environmental impacts, such as those to wildlife and ecosystems, are often first indicators or early warnings of adverse impacts on human health and safety.
- Human exposure, including those that can result in serious health impacts, is often due to environmental exposure (as opposed to exposure by direct use of or contact with a product), such as through the air, drinking water, and contaminated food sources.
- Continued introduction of chemicals into the environment places heavy technical, regulatory, legal, and financial burdens on local communities and agencies that must meet certain environmental standards or be in violation of the law. For instance, investing in higher levels of wastewater treatment to remove the many toxic substances from today's consumer products would cost California's more than 300 treatment plants hundreds of billions of dollars and, in the end, may not be technologically feasible.

§ 69501.1 (19)(A)2. and **§69503.2(a)(1)(A)h.** In earlier comments to DTSC, CHANGE offered suggestions to ensure and strengthen the consideration of environmental endpoints for the CoC and Priority Products lists. We support the addition of “degradates, metabolites, and reaction products” in the definition of a chemical, and consideration of a CoC’s ability to degrade, form reaction products, or metabolize into another CoC or chemical that exhibits one or more hazard traits and/or environmental or toxicological endpoints.

As already stated, CHANGE is deeply concerned by the omission of California's 303(d) list of impaired waterways and related contaminants. Other concerns regarding environmental endpoints include the following:

§ 69503.3 (g) CHANGE strongly opposes the language in this section and urges that it be stricken. There is no reason to restrict the universe of CoCs to be considered in the first round of the Priority Products categories as the program gets underway. In fact, by requiring that chemicals in consumer products on the initial Priority Product list(s) (those prior to 2016) meet criteria described in BOTH sections §69502.2 (a)(1) and (2), DTSC effectively ensures that water pollutants will not be included because there are no ecotoxicity lists that are equivalent to the human PBT and CMR lists described in section §69502.2(a)(1). Consequently, pollutants on the 303(d) list, solvents, metals such as copper or zinc, and other common surface water and groundwater contaminants will be omitted. If a chemical appears on the CoC list, this should be sufficient for a consumer product containing that chemical to be considered for prioritization.

What DTSC does in the first few years that these regulations are implemented will be critical to setting the stage for their future effectiveness and that of the Green Chemistry Initiative as a whole. For this reason, limiting the Priority Product list in this way is both inappropriate and sets a troublesome precedent for decision-making by future DTSC staff and leadership. It also substantiates concerns that many in the water community – public advocates and water agency personnel – have expressed over the years, namely that environmental concerns will not be addressed with adequate vigor. For these reasons, CHANGE strenuously urges DTSC to strike §69503.3(g).

§ 69501.1(a)(3)

It should be made explicitly clear that the definition of “adverse air quality impacts” includes both indoor and outdoor air quality impacts.

**Occupational health and worker protection of workers
must be more consistently incorporated into the regulations.**

§ 69501(b)(2), Page 4, lines 17-21

This section of the draft exempts products placed into the stream of commerce “solely for the manufacture” of a consumer product exempted from AB 1879. There is no reason a product used to make an exempted product should not be subject to the regulation – the statute excludes certain exempt products, not all chemicals used in their manufacture. This is an example where workers, who should be granted equal protection in the regulations, would be exposed to CoCs that others would not. We strongly object to this section and recommend that it be deleted.

§ 69501 (b)(3) Page 4, lines 22 – 23

Workers in California face hazards related to the manufacture, storage, or transport of products in the state, regardless of where those products are eventually sold. Hence, the regulations must apply to all products manufactured, stored, or transported in California, whether they are sold here or not.

The ISOR argues that the regulations are meant to design "consumers" from harmful chemicals in products. But consumers are not only individuals – businesses are consumers as well, buying chemicals and other products for manufacturing purposes in the state.

CHANGE has consistently objected to this section that exempts products that are manufactured or transported in California, but not sold here. This will expose workers who make the products and communities through which the products are transported to hazards that the regulations are meant to prevent. Workers and fenceline communities are members of the public and entitled to equal protection from harmful substances.

Any product that is manufactured here, whether it is sold here or not, will have an impact on the environment and public health. This section as drafted subverts the statute's goal of incorporating life cycle thinking. Life cycle is defined in 69501.1 (a)(39) to include manufacture, transport and distribution. In 69503.2 (a)(1)(B)4.a., “manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices” as Product Prioritization Factors.

We support the earlier comments from GRSP member Julia Quint, who has pointed out the unethical nature of excluding a consumer product that is "passing through" California. She wrote: “In contrast to customers, clients and members of the public who may be exposed for short periods of time to low concentrations of consumer products when they are in workplaces on an infrequent basis, workers who use the products are typically exposed to much larger quantities, on a daily basis, for years.”

§ 69501.1(a)(6), Page 6, lines 4-5

CHANGE supports the language that states, "Public health includes occupational health." This is consistent with the definition, understanding, and practices of public health.

§ 69501.1 (a)(22)(A), Page 8, line 32

DTSC should ensure that the definition of “Consumer Product” makes clear that chemicals and products used in the workplace, including bulk purchases, are included.

Add language under a new 69501.1(a)(22)(A)4. to read: Chemicals and products used in the workplace, including bulk purchases.

§ 69501.1(a)(53)(A)2., Page 12, lines 14-15

We support this section where "reliable information demonstrating the occurrence of exposures to a chemical" includes monitoring data that shows the chemical to be "present in, or released from, products used in or present in the home of places of employment."

§ 69501.5 (entire section) Pages 18 – 20)

We support this section that will make information available on DTSC's website, which will enhance workers' right to know about the hazards of products they use, and the Injury and Illness Prevention Programs (IIPPs) their employers must prepare.

Unfortunately, the information only will be available in English. This does little for the many people in the state with literacy issues in that language. We recommend that the list of chemicals of concern and priority products should be available at least in Spanish. Other government agencies do this (e.g., Cal/OSHA, DLSE).

§ 69505.5 (f)(2)(B)

This section requires a description of how safeguards provided by other federal or state regulations were considered in AAs. DTSC should add language here that does not permit AAs to rely on outdated and inadequate occupational exposure limits in the development of a safer alternative chemical or product.

§ 69506.4, Page 54

Product information for consumers, as specified in this section, also needs to be made available to workplaces. “Consumer products” are used in workplaces and by workers every day. They have as much right to know about hazardous chemicals and products as others, including other consumers.

Workers are appropriately included in the definition of “sensitive sub-populations” .

§ 69501.1(a)(58) Page 13 lines 19-25

CHANGE supports the inclusion of language in this definition that identifies workers as a sensitive sub-population when they experience greater chemical exposures due to the nature of their occupation. It recognizes that occupational hazards often lead to greater and longer exposures than those encountered in other settings (e.g., someone cleaning their own home). The exposures can be both higher and more frequent, making the hazard significant.

The wording in this section could and should be improved, however because workers face increased hazards not only because of the “nature of their occupation” but also because of the specific tasks or activities they perform at work. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. It’s what they actually do that matters.

Accordingly, CHANGE recommends changing the last sentence of the definition of sensitive sub-population (page 13, lines 23-25) as follows:

Current language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures or workers with greater exposures due to the nature of their occupation.

Suggested language: "Sensitive populations" also includes persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures, or workers with greater exposures **than the general population, due to the nature of their occupation and specific duties.**

The definition of “sensitive sub-populations” should be expanded to include women of reproductive age.

We also believe women of child-bearing age should be added as a sensitive sub-population. If we are concerned about exposure to chemicals at vulnerable windows of development (as we should be), then we must protect the woman who may become pregnant. The first weeks of gestation are a time of rapid development for the fetus and therefore also a time of critical vulnerability to harm. Consequently, many hazards to normal development threaten the fetus *in utero* early in pregnancy including before a woman may know she is pregnant. To protect the fetus, women of reproductive age must also be protected in addition to women who already know they are pregnant.

It should also be noted that children fathered by men who work in some occupations with high chemical hazards are at higher risk for birth defects. See Desrosiers, T.A., et al. (2012) "Paternal occupation and birth defects: findings from the National Birth Defects Prevention Study", *Occupational and Environmental Medicine*, 69(8): 534 – 542; and also Olshan, A.F., Teschke, K., & Baird, P.A. (1991) "Paternal occupation and congenital anomalies in offspring", *American Journal of Industrial Medicine*, 20(4):447 – 475.

DTSC actions, as well as innovation, will be hampered by dependence on “available information.”

The draft regulations give preference to information that is already “available.” Furthermore, prioritization and other decisions are influenced by, and are in fact dependent on, the current availability of safer alternatives. This sends the wrong signal to the marketplace and in fact runs counter to the goals of the SCP program by deterring innovation and the development of new alternatives. It could be interpreted to mean that no information implies a CoC is "safe." DTSC should not unnecessarily limit their decisions based on the availability of a safer alternative, especially in the regulatory response phase.

Much of what we are learning about potential harmful effects from chemical exposure is based on science that has emerged (and is emerging) quickly in recent years. New chemicals, and existing chemicals that have not been sufficiently studied, frequently lack the data sets that the definition of "safer alternative" could be interpreted to require.

There are many instances where DTSC’s decisions and regulatory actions will be limited by the lack of available information. By giving preference to, and relying on, the current availability of chemical data, instead of exercising the Department’s authority to request new information, DTSC will find itself promulgating the

data gap that continues to limit innovation or the development of green chemistry based alternatives. It also ensures that the burden of proof remains on the regulatory agency to demonstrate a chemical's hazards, not on the companies making the chemical or product containing the chemical to demonstrate it will not cause harm.

The SCP program should formally identify chemicals with little or no toxicity information as lacking adequate safety data. Furthermore, DTSC should use its call-in authority under AB 1879 to require the generation of new health and environmental data in order to accurately identify CoCs and safer alternatives and to make appropriate regulatory responses. DTSC should exercise this authority as early as possible in the program's implementation.

§ 69501.4(a)(3)

§ 69501.4(a)(4)

§ 69501.4(a)(3)(b)

Much of the information about chemicals that is needed by DTSC and the public is already known by manufacturers in-house, and should be required to be submitted to DTSC. While DTSC's effort to obtain existing or new information is laudable, the language should be strengthened so it is a requirement for responsible entities. Throughout these sections, "request" should be replaced with "require."

§ 69502.2(b)(3)

This is an example where DTSC could, instead of merely considering "the availability of reliable information to substantiate the potential adverse impacts and exposures," require responsible entities to provide or produce the needed data for additions to the CoC list. This would reverse the burden of proof and bring more information forward sooner.

§ 69503.2(a)(2)

Rather than rely on availability of information, DTSC should use this as an opportunity to require responsible entities to provide or produce information needed to make an informed decision.

§ 69506.2(a),(b)

CHANGE strongly supports the language in these two sections that gives DTSC authority to require the provision or development of needed additional information. This information would be even more useful earlier in the process.

**The regulations are silent about how to treat chemicals
for which we have insufficient or no information.**

CHANGE continues to contend that chemicals for which there is little or no toxicity information can reasonably be considered CoCs under AB 1879, giving DTSC the authority to request further information so these chemicals can be assessed.

In the absence of such a minimum data requirement, the regulations should at the very least create a mechanism to identify these chemicals – a "yellow flag" that sends a message to the market and the public that they are under-studied and not necessarily "safe" or non-toxic.

The draft regulations rely too often on an over-reliance on simply reducing or containing chemical exposures instead of preventing their use.

We recognize that exposure data will be considered in the SCP implementation, but the innovative intent of AB 1879 is to base decisions on reducing hazards as the highest priority. That is, if a substance is dangerous, this is reason enough to act to restrict its use. Otherwise, it is far too easy to fall into a strategy of “containment” whereby exposures continue to be allowed based on a plan of containing a chemical to reduce or contain exposure. This approach unfortunately fails too often; for example, this can be easily seen in workplaces where workers still have to handle toxic chemicals and limiting harm is the most common solution, rather than eliminating a hazard. Moreover, safety standards are generally inadequate and often out-of-date.

Moreover, "containment" or "control" fails to drive the development and use of less toxic chemicals, one of the overarching goals of both the SCP regulations and California's broader Green Chemistry Initiative.

While CHANGE recognizes that restricting exposure by confining a chemical within a product may be an improvement and is in keeping with DTSC's approach of not prescribing how manufacturers address the CoCs in their products, CHANGE has consistently advocated that engineering safety measures or administrative controls be viewed as *interim actions*, not permanent solutions to reduce danger to the public and the environment while inherently less hazardous alternatives are developed.

§ 69506.7 (a) Page 57

CHANGE recommends that any engineered safety measures or administrative controls imposed by DTSC in in this section be considered *an interim action* until a more sustainable solution is found.

Current language for § 69506.7 (a)

The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts.

Suggested language for § 69506.7 (a)

The Department may, under subsection (b), impose requirements that control access to or limit exposure to Chemical(s) of Concern in a selected alternative product, or a Priority Product for which an alternative is not selected, to reduce the likelihood of adverse public health and/or environmental impacts as an interim action while a solution to eliminate the hazard is found.

§ 69501 (a) Page 4, lines 8-12

Current language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to limit exposure to, or the level of adverse impacts posed by, the Chemical of Concern in the product.

Suggested language: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to reduce the use of toxic chemicals, or the level of adverse impacts posed by the Chemical of Concern in the product.

§ 69501.1 (a)(11)(D) Page 7 line 24

Current language: Any other change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

Suggested language: If Removal, Reformulation, or Redesign is not feasible, a secondary strategy of another change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

§ 69505.3 (b)(2)(A)1 Page 41, lines 30-35

Current language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of “alternative” under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product and/or reduce or restrict exposures to the Chemical(s) of Concern in the Priority Product.

Suggested language: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of “alternative” under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product. If a responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, they should then seek to reduce or restrict the potential for release of the Chemical(s) of Concern, leading to human or environmental exposures, as an interim action until a less or non-hazardous alternative is developed.

Definition of "technically and economically feasible alternative"

We agree with others who have asked for greater clarification about the definition of "technically and economically feasible alternative," and that they should be defined and evaluated separately.

If something is technically possible, this should be the standard for whether it should be considered.

§ 69501.1 (a)(59) Page 13, Line 27-32

CHANGE strongly objects to the language in the definition of "technically and economically feasible alternative." Even if "significant reduction in a manufacturer's operating margin" and "meeting consumer demand" are defined, it requires numbers that can easily be manipulated to give an off-ramp to any responsible entity.

We urge § 69501.1 (a)(59)(B) be stricken: "The manufacturer's operating margin is not significantly reduced."

We urge the language in § 69501.1 (a)(59)(A) be amended by deleting "and to meet consumer demand after an appropriate phase-in period." Requiring a company to demonstrate consumer demand would limit timely options for alternatives especially if companies request delays to conduct consumer research.

Definition of “functionally acceptable”

This definition suffers from the same flaw as the definition of "technically and economically feasible alternative." The current draft would enable a responsible to cite its impacted operating margin as a reason to be exempted from pursuing safer products because "consumers have not been reasonably accepting of the alternative in the marketplace." This is a vague and undeterminable indicator that would be essentially impossible to define and measure. Who will judge what "consumers can be reasonably anticipated" to accept?

§ 69501.1(a)(31)(B) Page 9, Lines 35-36

We recommend the following language for the definition of “functionally acceptable”: *(B) “The product performs the functions of the original product sufficiently well that the product’s goals are reasonably well attained.”*

Definitions of "Chemical" and "Chemical Ingredient"

These important terms derive from AB1879. One goal in properly defining them is to ensure that they will reach complex nanomaterials in the event the Department identifies such materials as CoCs. Another is to ensure that the two statutory terms can both be used to identify chemicals of concern.

We appreciate the Department’s response to our suggestions as to how to improve the definitions that were used in prior draft proposed regulations. The Department essentially has adopted CHANGE’s recommendations, but with one discrepancy that can easily be fixed.

§ 69501.1(19)(A)(2)

The definitions currently provide that a chemical ingredient means “a substance comprising one or more of any **substance, element, ion, uncombined radical, degradate, metabolite, or reaction product.**” The problem is that the terms in bold are now disconnected from the qualifiers that exist in the first part of the definition, and so are seemingly too broad and perhaps even essentially undefined.

We suggest that this can be easily fixed by amending the definition of chemical ingredient in §69501.1(19)(A)(2) to read:

“a substance comprising one or more substances of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity.”

We believe this change, though minor, is important and that it will work. We appreciate the Department’s attention to this important detail, and request that this suggestion be implemented.

**Trade Secret Protection for Chemical Identify in
Hazard Trait Submissions**

CHANGE offers two comments on the proposed regulations in connection with trade secret protection for chemical identity in hazard trait submissions: one relating to the trade secret provisions and one relating to the definition of hazard trait submissions. Both of these comments are important to this issue.

a. Trade Secret Protection for Chemical Identity

§ 69510 (f)

The regulations provide in § 69510(f) that “. . . trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission.” We believe this provision is not discretionary but is mandated by AB 1879, HSC § 25257(f), including as applied to chemical identity in hazard trait submission. The reason chemical identity should not be claimed as a trade secret in a hazard trait submission is that doing so would disconnect the remaining disclosure of health, safety or environmental information from any particular chemical and thereby render it meaningless, useless and immune from any oversight by the public or market. It would defeat the obvious intent of the law to make the health, safety and environmental information about particular chemicals contained in hazard trait submissions available to the public and the market. Accordingly, CHANGE strongly supports this provision.

§ 69510 (g)

Unfortunately, however, the regulations also set forth an exception to this bar on trade secret protection for chemical identity. § 69510(g) provides that trade secret protection may be available for chemical identity in hazard trait submissions in the case of new chemicals or new uses of existing chemicals. CHANGE believes this exception is legally invalid and also unwise policy, and that it should be eliminated.

The exception is illegal under AB 1879. In that statute, the legislature struck a balance between the competing interests of the commercial importance of the confidentiality of chemical information on the one hand, and the need of the public and the broader market to have access to such information on the other. The balance struck by the law is that trade secret protection is available for most such information, but not health and safety information in hazard trait submissions. The latter is particularly important for public disclosure, because it is the very information most necessary to evaluate the safety and health effects of chemicals and chemical ingredients. There is no basis anywhere in AB 1879 for the Department to disregard the law in the particular case of new chemicals or new uses of existing chemicals. The law requires disclosure of health and safety information in all hazard trait submissions without exception, which must include chemical identity if the disclosure is to have any meaning or utility.

Moreover, the law is just good policy. The public and the market need access to hazard trait information for new chemicals and new uses just as much as they do for existing chemicals and uses.

The exception of § 69510 (g) should be eliminated.

Should the Department nevertheless conclude that this exception is legal and wishes to maintain it as a policy matter, CHANGE recommends the following modifications designed to give greater force to the competing interest in disclosure:

1. The exception should apply not to all proposed alternatives to a CoC, but only to those not chosen as preferred to the CoC. If an alternative is chosen as preferred to a CoC and is therefore going to be marketed in a consumer product, the public and the market need to know the safety properties of that alternative. That need for a marketed chemical outweighs the private need for confidentiality. If the alternative is not chosen and there shall not be marketed, then the commercial interest in that new, but NOT SELECTED alternative would be protected under this proposal. Though we believe an important oversight function of disclosure would be foregone by following this proposal, it would protect both the public when it is exposed to a chemical and industry's interest in keeping confidential new chemicals and uses that are not yet marketed.
2. All trade secret claims made under this exception should be time limited and subject to revalidation periodically, for example every 5 years. Because the legislature has clearly expressed the view that hazard trait submissions should be publicly available, it is particularly important in this case that they not be withheld on the basis of trade secret claims that could grow stale.
3. § 69510 (g)(2) permits a party to provide the Department with selective information about the properties and toxicity of the alternative. CHANGE suggests that this section require that ALL available data about the alternative, not just the information that is selected by the party seeking trade secret protection, demonstrate health and safety to the Department's satisfaction.

b. Definition of Hazard Trait Submission

§ 69501.1 (a)(33)

This provision by its terms only applies if a study or datum indicates “that a chemical manifests any hazard trait.” It does not apply if a study indicates that a chemical does NOT manifest a hazard trait. CHANGE believes that hazard trait submissions indicating that a chemical is non-toxic are just as important as those indicating a chemical presents hazards. The market and the public need to exercise oversight of study claims that a chemical is safe. They also need to know which chemicals are safer in order for the market to be able to select safer chemicals over more hazardous ones.

Current language: “When any study or datum indicates that a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission.”

Suggested language: “When any study or datum provides information relating to whether a chemical manifests any hazard trait, chemical identity is part of any hazard trait submission.”

Trade secret claims should be minimized.

DTSC is not providing any broad new leadership on transparency and trade secrets in the informal draft regulations, but instead relies on existing law in this area. CHANGE believes this will impair the program's ability to be fully trusted by all stakeholders. Nevertheless, DSTC can take some steps to reduce the amount of trade secret claims that will be allowed under this program, and CHANGE urges it to do so. One of the most valuable contributions this program can make is to make more information about chemicals available to the public and the marketplace.

Trade secrets should not be allowed for any health and safety or product ingredient information, nor for a

chemical's identification in hazard trait submissions; nor for other kinds of information such as AA methodologies that AA assessors might choose. Transparency of this information is important for accountability, for public confidence in the program and for the ability of the program to affect the market. Simply put, consumers, workers and other downstream users of chemicals have a right to know about and avoid the hazards found in the chemicals and products they purchase. Recent tests by Women's Voices for the Earth found that popular cleaning brands had hidden ingredients linked to cancer, reproductive harm and allergies. Workers and employers have had similar experiences with inadequate and inaccurate Material Safety Data Sheets.

Importantly, DTSC should not see transparency provisions as an effort to satisfy NGO's. DTSC itself should have acute concern with both the credibility and effectiveness of this program. Without enough transparency for the public and industry to understand the results of the AA Reports, the program will simply not convince the public that it is being properly protected, and hopes for broad impacts of analysis of "sentinel product/CoCs" will be unrealized because no lessons will be understood by the market.

We support the requirement that responsible entities must provide adequate justification for trade secret claims. We believe these requirements will discourage trade secret claims that are not warranted or of little value to the responsible entity, and we urge DTSC to retain these requirements.

We propose the following specific amendments to the regulations to implement these suggestions.

§ 69501.1(a)(60) Page 13, line 34

The definition of "Trade Secret" should provide that "Trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient" as specified in 69510(f), Page 76, lines 32-34.

§ 69505.5. (a)(6)(A) Page 45, lines 38-41

CHANGE strongly supports the language that, if an AA Report contains information "claimed by the responsible entity to be a trade secret, a separate, publicly available AA Report shall be submitted to the Department that masks claimed trade secret information only to the extent necessary to protect its confidential nature." This would protect valid trade secret claims, but at the same time provide a useful range of data so the material basis for the decision is explained in some way. We believe many industries are already familiar with such masking strategies, such as preparing disclosures to comply with securities laws, or voluntarily describing confidential technology in initial approaches to prospective business partners, even under confidentiality agreements.

§ 69505.5(d),(e),(h)(2) beginning Page 46

CHANGE strongly supports the requirements that compel the responsible entity to provide information in their AA reports on the Supply Chain (d); Facility Description and Location (e); and the identification of unavailable reliable information (h)(2). This information will help the market operate more efficiently.

§ 69505.6(e) Page 51, lines 38-40.

All notices issued by the Department should also be posted on DTSC website.

§ 69508.3(e) Page 73, lines 21-22

CHANGE supports the inclusion of this provision, which reads: "An accreditation body may not claim trade secret protection for its general admission process, curriculum, and educational approach."

§ 69510 Page 75

Regarding the Assertion of a Claim of Trade Secret Protection, CHANGE supports the range of information DTSC will require to ensure that trade secret claims are in fact valid and are not made frivolously. We believe these requirements will discourage trade secret claims that are not warranted or are of little value to the responsible entity.

§ 69510 (a)(8) Page 75, lines 31-34

CHANGE strongly supports this requirement for trade secret justification: "The estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering."

§ 69510(c)(2) Page 76, lines 18-20

CHANGE fully supports making a redacted copy of the documentation related to trade secret claims, excluding the information being submitted for trade secret protection, available to the public. This will allow the public, local agencies, employers, workers, and other end-users to gauge the degree to which information is being kept confidential and allow them to make better consumer, business, or regulatory decisions. Since no trade secret information will be included, CHANGE recommends that DTSC make the documentation available in all cases, rather than "at DTSC's discretion."

§ 69510(f) Page 76, lines 32-34

CHANGE strongly supports the provision that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission. This explicit language is derived directly from the enabling statute, and reflects the importance of making this information publicly available.

§ 69510.1 Page 77

CHANGE recommends that DTSC add language here that the public shall be informed when companies' trade secret claims have been approved by DTSC so that the public knows that complete information about the chemical is not available.

A strong firewall is necessary between Responsible Entities and those who complete Alternative Assessments

The lack of transparency and oversight in the production and review of Alternative Assessment reports is breathtaking. Not only will DTSC permit responsible entities to claim substantial information about the chemicals in their products as confidential, shielding it from consumers, public researchers, and the marketplace, but the regulations will allow responsible entities to conduct their own AA reports with no public oversight or input. Instead, a cumbersome oversight structure is proposed for which DTSC does not have the resources.

Transparency in how the program is managed is important both for accountability of decision-making and for the ability of the program to correct the market failure caused by lack of publicly available information in the market. Moreover, without transparency, there is a substantial risk that the program won't be seen as credible by the people of California.

CHANGE has long maintained that Alternatives Assessments should not be conducted by the makers or users of toxic chemicals. Since AAs contain quantitative and qualitative data, the assessment can be easily “gamed” to arrive at a pre-determined outcome. We continue to believe that the best, unbiased way to conduct AAs would be for manufacturers to pay into a fund that is then administered by the department to hire one or more AA experts to conduct the AA, or for DTSC to conduct the AAs itself. This system would eliminate conflicts of interest and would provide DTSC with unbiased information prior to issuing a regulatory response. It would build expertise at the state in conducting AAs for following and developing best practices. And it would be more cost effective for DTSC to manage the program itself instead of the vast oversight responsibilities that will be needed under the current draft regulations.

An alternative method to provide more assurances of an unbiased AA would be to require manufacturers to work with outside, certified AA experts who could conduct the AA. Yet another method would be to require independent third party verification of AA reports performed by industry. CHANGE has suggested that companies that conduct AAs with no trade secret claims and make the reports public could be exempt from third party oversight. Some BizNGO members have suggested a peer review panel to provide quality control on AAs. None of these suggestions is reflected in the formal draft regulations.

Rather, the department has decided that all AA reports may be done by manufacturers, so long as the person performing the AA meets certain requirements and has been certified by an accreditation body. While we understand that the Department hopes this certification will lead to unbiased outcomes, we disagree. Being certified by an independent body will not guarantee against mischief or even bias in AA reports. Moreover, the department does not have the resources required, nor the expertise, to fully review every AA report. The time and money required to do so will slow the pace of product prioritization and lead to consumer products containing CoCs remaining in the market for a longer period of time, increasing hazards for all Californians’. Requiring either independent AAs or third party review will allow the Department to spend its limited resources on prioritizing products and issuing the appropriate regulatory responses.

If DTSC proceeds with its proposed accreditation body model, CHANGE recommends the following changes:

§ 69508 (g)(1) Page 67, line 17

CHANGE supports the provision that a certified assessor may not be in responsible charge of conducting an AA and/or preparing a Preliminary or Final AA Report, or both, if the certified assessor has an ownership interest in the responsible entity whose product is the subject of the AA. We believe, however, that there should be no permissible equity stake as any amount would increase the chance of conflict of interest. Accordingly, the \$10,000.00 threshold should be eliminated.

§ 69508.1 (b) and (c) Page 70, lines 4-8

CHANGE supports the provision that any entity that seeks designation as an accreditation body must be independent of, and may not hold any stock or ownership interest in, any consumer product manufacturing, importation, distribution, or retail business (except colleges, universities, or their subdivisions as noted).

§ 609508 (b)(2)(A) Page 66, lines 22-27

CHANGE supports the requirement for at least 20 hours of continuing education during each two-year accreditation period for assessors, including two hours each period in professional ethics.

§ 69508.1(a)(5)(D) Page 68, line 26-32

CHANGE supports the requirement that accreditation bodies demonstrate expertise in public health among other skill sets. But we believe that “pollution prevention” and “maternal and child health” should not have been deleted from the previous drafts and recommend that they be reinstated.

§ 69508.1(a)(5)(E) Page 68, line 33-42

CHANGE supports the requirement that accreditation bodies demonstrate expertise in professional ethics.

Transparency must be maximized in Alternatives Assessment Reports.

CHANGE is very concerned that responsible entities can do their own AAs. While the proposed accreditation process builds in some accountability, the fact remains that a responsible entity will have a vested interest in a specific outcome of an alternatives assessment, and DTSC may not have the resources to adequately audit the many AA reports that will be generated. Moreover, the expected prevalence of trade secret claims is very likely to result in AA Reports that cannot be meaningfully evaluated by the public or other parties. Under these circumstances, the public is unlikely to have confidence in the decisions made by the program.

CHANGE has long advocated for the public’s right to know about chemicals in the products they use and the impacts of those chemicals on human and environmental health. We recognize businesses may need to claim information about the ultimate makeup or formulation of some of their products as a trade secret to maintain a competitive advantage in the marketplace and to attract investment in new, innovative chemicals and products. We further recognize that *the Safer Consumer Products Regulations* must conform to current legal trade secret protections.

However, given that AAs will be prepared by manufacturers with a vested interest in the AA's outcome, as well as DTSC’s limited resources to review those AAs, the Department should rely on the public, as well as a manufacturer’s competitors, to ensure that the AA is factual and represents a good faith effort to reduce the use of toxic chemicals. Without reasonable limits on the information that can be claimed as confidential in AA Reports, there is no way for the public to maintain its critical role as watchdog over this important part of the program.

CHANGE strongly supports the department’s explicit language that health and safety information and chemical identity in relation to health and safety data may not be claimed as confidential. We also support the fact that a version of submitted AA reports will be made public and that trade secret information will be masked only to the extent necessary to protect its confidential nature as specified in 69505.5 (a)(6)(A).

However, the language in 69505.5 (a)(6)(A) is vague. It is not clear what information is subject to masking and what it means to ensure that the public has a substantive understanding of a company’s workplan, the actual AA, and the ultimate conclusions of the AA. Furthermore, there are no clear steps that companies should take to ensure that they meet these provisions.

We therefore strongly recommend that the Department develop specific guidelines for masking strategies as part of the Alternative Assessment guidance published the adoption of these regulations. This guidance should clarify the types of information for which masking is acceptable and provide recommendations for compliance, including but not limited to using ranges to obscure specific formulations.

While a growing number of companies recognize that full public disclosure about their products actually creates competitive advantage, nothing in the regulations encourages this. Requiring companies to mask trade secret information in a way that promotes the public's understanding of AAs is a positive step. Still, DTSC should provide incentives for voluntary full public transparency. For example, manufacturers could get a streamlined review process in exchange for forgoing all trade secrecy claims.

Importantly, since regulatory responses are based on the content of AA reports, it is essential that there be a mechanism for the public to register questions or objections to information in them. The Department should determine how the contents of AA Reports can be meaningfully shared with the public, and include a public comment period following the submission of AA Reports. A publicly available executive summary of both the Preliminary AA Report and Final AA report should be accompanied by a public comment period before DTSC accepts the findings of either document.

Ultimately, CHANGE believes that when it comes to potentially toxic chemicals in a consumer product, public, worker, and environmental health trumps an individual manufacturer's desire for confidentiality. We appreciate the Department's recognition of this and its attempts to facilitate a balance between the public good and legitimate business concerns. However, successful balance requires proper guidance, a variety of options, and public input, so that both businesses and the general public can have confidence in the program.

§ 69505.1. (g) Page 38, Lines 17-21.

CHANGE strongly supports the requirement of notification when a Chemical(s) of Concern is/are removed from a priority product, even when a responsible entity reformulates without adding or replacing a substitute chemical. This notification is necessary for the public and the Department to assess the program's overall success in achieving its goal to spur innovation and develop safer consumer products. Without receiving notification, neither the public nor the Department will be able to assess the true and complete impact of these regulations which may come under budgetary scrutiny or attack in the future.

§ 69505.1. (g)(2)(F) Page 38, Lines 35-36.

CHANGE supports the requirement for the responsible entity to submit notification of the measures it will take to "ensure the product that contained the Chemical(s) of Concern is no longer placed into the stream of commerce in California." This is an important protection for EJ communities since companies often dump old products into dollar or discount stores located in poorer communities. In fact, CHANGE strongly encourages the Department to institute fines to companies who continue to sell products containing Chemical(s) of Concern after notifying the department that they have been removed. Experience with California's Proposition 65 program has demonstrated that a combination of on-going surveillance and fines are needed to ensure companies comply with the law.

§ 69505.1. (g)(2)(G)2. Page 38, Lines 40-42.

CHANGE supports the requirement in the regulations that requires responsible entities to submit "laboratory analytical testing, quality control, and quality assurance protocols used to detect and measure the Chemical(s) of Concern in the product that ensures the Chemical(s) of Concern have been removed."

§ 69505.3 (b)(1)(C)1. Page 41, Lines 21-23

CHANGE strongly supports the requirement that the responsible entity shall determine if the Chemical(s) of Concern or substitute chemical(s) is/are necessary to meet the Priority Product's requirements. This analysis should be explicitly required in the AA Reports.

§ 69505.5. (d) Page 46, line 19

CHANGE supports the inclusion of comprehensive supply chain information in AA Reports.

Some timelines can be shortened to avoid unnecessary delays in program implementation.

In places, the draft regulations are overly generous to responsible entities in the allowed timelines and the granting of extensions. In addition, the regulations allow all DTSC actions to be stayed during a dispute until resolved. We are concerned that allowing disputes at any stage can lead to frivolous delay tactics by those entities that are regulated. It is clear that DTSC will focus on chemical/product combinations that have enough evidence to suggest a high hazard to the public, and the public has a right to know which of these product/combinations are of sufficient concern to warrant DTSC's request for an AA.

§69503.4 (e) Page 30, Lines 35-38

Allowing 180 days to post the initial proposed list of Priority Products the effective date of the regulations is too long, especially since we have heard several times from DTSC that there will only be two to five product categories in the first round. CHANGE believes 90 days should be sufficient for the initial group of product categories to be identified and posted.

§69507.6 (d) Page 65, Lines 13-15

This section of the draft states: "The Department shall issue an order specifying its decision on the merits of the Request for Review within one hundred and eighty (180) days from the date it grants the Request for Review." CHANGE believes 180 days is much too long a time period for DTSC to make this kind of decision, especially since DTSC will have already had 60 days to consider whether to grant a Review or not. A total of 90 days should be more than adequate for DTSC to act.

"Economic Impacts" must capture all appropriate costs, including to public health, occupational health, and the environment.

DTSC should use consistent language about economic impacts throughout the document. When considering economic impacts, the regulations should ensure that all relevant impacts to public health, occupational health, and the environment are accounted for.

§ 69501.1 Page 4

We recommend re-inserting a definition of "Economic Impacts" using the following language: *"Economic Impacts means internalized and externalized costs to the public, families, the environment, public health, workers, government agencies, businesses, consumers, and the taxpayer."*

§ 69505.4(a)(2)(A) Page 43, Lines 8-17

Too often, extraction is left out of the considerations when talking about a life cycle analysis. "Extraction of raw materials" should be added to the life cycle impacts listed in 1.-7. This is an often significant life cycle impact that should not be ignored.

§ 69503.2 (a)(1)(B)4.a. Page 26, Lines 35-36

This is another example where "extraction of raw materials" should be added so this section reads: ***Extraction of raw materials, manufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices.***

§ 69505.4(a)(2)(C) Page 43, Lines 28-41

This section requires responsible entities, during the second stage of an AA, to "take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered."

Cost impacts need to explicitly include externalized costs related to public health, occupational health, and the environment which will be borne by society and the taxpayer stemming from the life cycle factors cited in § 69505.4(a)(2)(A). These cost factors should be listed in (C) so there is a complete understanding of the economic costs to retain a Priority Product despite the continuing presence of a CoC.

§ 69501 (b)(1) Page 4, Lines 15-16

DTSC should specify that being placed "in the stream of commerce in California" includes internet / online purchases.

§ 69501.1(a)(36) Page 10, Line 16

Add the words "or entity" to the definition of "Importer" so it reads: "*Importer means a person **or entity** who imports a consumer product into the United States.*"

CHANGE is not convinced that regulation automatically leads to negative impacts on a responsible entity's balance sheet.

For example, Market Watch -- <http://www.marketwatch.com/story/regulation-may-have-little-jobs-impact-2012-08-06?pagenumber=1> -- reported on August 6, 2012 that it is not clear that regulation hurt a business's bottom line or leads to a loss of jobs. It was noted that while there are clearly people who lose jobs from regulations in the U.S., there are also people who gain jobs as some regulations have created entire new industries such as catalytic converter manufacturing. Similarly, we should have every reason to expect the *Safer Consumer Products Regulations* will spawn a new industry of alternative analysis and assessment that leads to innovative products and processes in California.

In fact, Cary Coglianese, a regulation expert at the University of Pennsylvania Law School, says: "The net effects of regulations on employment are generally rather negligible." Some studies about environmental regulation show that, on balance, regulation has had little or positive impact on overall industry employment. Data from the U.S. Department of Labor indicate that employers cite government regulations and intervention as the reason for layoffs as employers cited governmental regulations/intervention as the reason for less than 1% of layoffs.

There also is important evidence that the anticipated costs of regulation generally are overestimated, often substantially. For example, see "*Not Too Costly, After All: An Examination of the Inflated Cost-Estimates of Health, Safety and Environmental Protections*", by Ruth Ruttenberg and Associates, Inc. for the Public Citizen Foundation, 2004.

Beyond this, it is not in society's best interest to preserve a job that has more negative impacts than positive ones. We don't want to produce something that is toxic just because it provides a job. Regulations are meant to promote overall social welfare which can include a variety of important societal benefits, not just employment. The potentially substantial health and worker productivity benefits associated with regulations which should be

factored into any cost-related analysis. The *Safer Consumer Product Regulations* are stimulating the development of better jobs, not less jobs.

A key principle driving Regulatory Responses by DTSC gives preference to responses providing the greatest level of inherent protection.

§ 69506 (b) Page 52, lines 10-14

"In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection."

CHANGE strongly supports this important principle that will guide DTSC regulatory responses. Preventing harm is easier, cheaper, and more effective than managing harm after it has occurred. This key language clarifies that the ultimate goal of the *Safer Consumer Product Regulations* is the elimination of toxic chemicals and the development of safer, green chemistry-based alternatives.

Enforcement must include significant penalties.

§ 69501.3 (a) – (c), Page 17, lines 1-21

We support these sections which require all information submitted to DTSC under the penalty of perjury to be signed by the person who prepared the information as well as the owner of the company or an official or authorized representative. It is an effective method to ensure the company's responsibilities under these regulations are integrated into the company's activities. This is consistent with requirements for California's workplace Injury and Illness Prevention Program rules and studies showing that programs are more effective with written management commitment that comes from the top.

In addition, CHANGE recommends that responsible entities be required to post a bond or otherwise provide proof of insurance regarding the information they submit to DTSC.

§ 69501.2(d)

If the most stringent or only punitive measure to address "Failure to Comply" is a DTSC website listing, this is inadequate to compel compliance by responsible entities. "Failure to Comply" and "Failure to Respond" should trigger more meaningful penalties, including significant fines.

Furthermore, warning responsible parties that they are not in compliance and will be so listed on DTSC's web site takes up Department resources and time. We would suggest that it is up to those parties to comply with the regulation and that not doing so should result in listing without warning, until they rectify the situation. In our view, this is not only fair, given that companies have the responsibility to be familiar with the law and heed it, but also appropriate given the current economic burden on public agencies and DTSC's limited funding and resources.

A robust end-of-life management program is important and will contribute to positive changes in the marketplace.

§ 69506.8(a)(2) Page 57, Lines 38-41

Concerning the End-of-Life Management Requirements in regulatory responses, CHANGE strongly supports the language that requires the responsible entity to “fund, establish, and maintain an end-of-life management program” including a detailed plan and financial guarantee mechanism, as well as compensation to retailers and other persons who agree to administer or participate in the collection program.

In addition, CHANGE believes responsible parties should also be required to estimate the lifetime of the applicable products they are managing and provide DTSC with a copy of their product stewardship plan.

§ 69506.8(d) Page 59, Lines 14-17

CHANGE objects to this provision which would permit a responsible entity to request an exemption from end-of-life management program requirements by demonstrating to DTSC that such end-of-life program "cannot be feasibly implemented for the product." Such an off-ramp will surely lead to claims that end-of-life programs are in fact not feasible. DTSC would then have the job of deciding if the responsible entity had adequately "demonstrated" its claim. An end-of-life management program should be required in all cases, with the responsible entity providing limitations and mitigating factors in the end-of-life management plan.

An inventory recall mechanism should be included in Regulatory Responses.

§ 69506.6 Page 55

There is no provision for an inventory recall in the Product Sales Prohibition section. Additional language should be added here to ensure that phased-out products, with a consumer label or not, are not dumped into discount stores and low-income areas.

AA Report Supplemental Information Requirements

§ 69506.2 (a) and (b) Page 5, Lines 30-39

CHANGE supports these provisions allowing DTSC to require responsible entities to provide supplemental information or to take steps to fill data gaps.

Advancement of Green Chemistry and Green Engineering

§ 69506.9

CHANGE supports the draft regulations that give the Department the ability to require responsible entities to initiate a research /development project or fund a green chemistry challenge grant.

Dispute Resolution

§ 69507(b) Page 62, Lines 33-36

CHANGE supports the language in the draft regulations that require responsible entities pursuing a dispute to follow the specified procedures or forfeit the right to further contest the dispute administratively.

CHANGE recommends that when a dispute is filed, DTSC make public the reason the dispute is being filed, as well as continue to inform the public as to where the matter stands. In other words, there should not be a blanket silence when a dispute is filed. Instead, there should be a summary of why the chemical/product combination was prioritized, and a current update about how the dispute is being resolved. Without provisions like this, companies will have a green light to pursue frivolous disputes, wasting scarce DTSC resources and undermining the public's confidence in the process.

Dispute processes should include short timelines to minimize costs to both sides. The current draft allows for far too much delay by the responsible entity for a straightforward task.

Priority Product Work Plan will limit DTSC's ability to respond to new hazards.

§ 69503.3 (f)

This new provision requires DTSC to develop and issue a Priority Product Work Plan by 1/1/14 that describes the product categories that the Department will evaluate to identify products to be added to the Priority Products list during the next six (6) years.

This provision has several serious flaws. First, it unnecessarily commits DTSC to a small number of consumer products, allowing the vast majority of products to continue to be marketed without any incentives to move away from CoCs. Second, it would prevent DTSC from responding to new science about CoCs and the products that contain them. Third, it is predicated on the current level of DTSC resources that may change over time. In the initial pilot stage, DTSC will identify no more than 5 priority products, in large measure because of resource constraints. If budget forecasts improve, DTSC should be able to ramp up the program as much as possible.

CHANGE opposes tying DTSC's hands with this restrictive requirement.

If a Priority Product Work Plan remains in the regulations, DTSC should not be limited in the number of possible priority products it will list. Rather, an open-ended list of potential products should be posted, allowing DTSC the flexibility to initiate the search for safer alternatives as circumstances and resources permit.

A DTSC Priority Product Work Plan must include an opportunity for public comment.

###



October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Sent via e-mail to: gcregs@dtsc.ca.gov

Re: Division 4.5, Title 22, California Code of Regulations Chapter 55. Safer Consumer Products – Proposed Regulations, R-2011-02 (July, 2012)

Dear Ms. Von Burg:

On behalf of the California Grocers Association and its member companies, I respectfully submit the following comments relative to the Safer Consumer Products (Chapter 55 of Division 4.5 of Title 22, California Code of Regulations) July 2012 Proposed Regulations (Green Chemistry).

CGA is a non-profit, statewide trade association representing the retail food industry since 1898. CGA represents approximately 400 retail members including chain and independent supermarkets, convenience stores and mass merchandisers operating over 6,000 food stores in California and Nevada, along with approximately 300 grocery supplier companies.

We appreciate the Department's efforts in seeking to accomplish the goals outlined by statute. However, we have significant concerns that without clarification and revision California grocery retailers will not be in a position to determine their obligations and requirements under the regulation and in many instances will find compliance impossible when it is determinable. We recommend several revisions we feel are critical to ensuring success of California's ambitious Green Chemistry program.

I have divided our comments into categories, beginning with definitional issues that if resolved, could help alleviate concerns noted in subsequent comments. In addition, where possible I have attempted to include specific examples of how the proposed language impacts grocery retailers in California.

Definitions – Section 69501.1

"MANUFACTURER": This term is defined in the proposed regulation (Section 69501.1(a)(41)) as not only a person who manufactures but also one who, "...controls the specifications and design of, or use of materials in, a product." An attempt is made to clarify the term in the Initial Statement of Reasons (ISOR) through use of an example – a private label retailer (p. 29, line 14). It appears later in the ISOR, however, that not all private label retailers are considered manufacturers for the purposes of this regulation when an exclusion is outlined for a person who orders a product and merely controls which available optional components, etc... are included (p. 29, line 20 et seq).

This issue must be clarified in the proposed regulation. The term “manufacturer” should not include any person or entity other than the actual manufacturer of a product. It is unrealistic to expect a private label retailer to have knowledge of specific ingredients of products they do not themselves manufacture, even if they specify characteristics like scent, color, etc... The private label retailer does not control the formulations used to achieve specified characteristics, the manufacturer does. Even in cases where a private label retailer specifies that a product should be free of a given chemical (BPA free for example), they are not in a position to determine what chemical(s) a manufacturer uses instead. In most cases, formulations are proprietary to the true manufacturer as would be any decisions about reformulation, regulatory responses, etc...

The regulation must be modified to use the following definition in Section 69501.1(a)(41):

“Manufacturer” means any person that manufactures a product, or any person that controls the manufacturing processes and chemical ingredients or formulation used to produce the finished product. The use of quality, performance or design specifications, such as color, size or material, does not constitute control.

This suggested verbiage serves to ensure that those with actual knowledge of and control over specific formulations and chemical usage are assigned an appropriate level of responsibility. In the event of noncompliance by the manufacturer, the regulation elsewhere includes other responsible parties that could choose to stand in the shoes of the manufacturer.

Duty to Comply – Section 69501.2

While we appreciate the tiered approach to compliance duties, absent clarification of the definition of manufacturer, retailers could be required to undertake significant duties even though they lack actual knowledge about chemical usage, product formulations, or realistic options for reformulation or other regulatory responses. For example, a retailer would have no idea which products must be removed or replaced pursuant to 69501.2 (b)(1) or (b)(2) as the retailer does not generally have access to formulations. Likewise, a retailer considered a manufacturer under this section would generally have no information about brand and product names that may be in use by other retailers as required in 69501.2(b)(1)(D) and (b)(2)(D). Compliance would be impossible at best.

In addition, if considered a manufacturer, many retailers will be unable to provide information regarding all entities other than final purchaser/lessee to whom covered product(s) have been sold as required in 69501.2(b)(1)(B) and (b)(2)(B). Many consumers shop for “bulk” products at grocery retailers but they are not the final purchaser. Rather, they purchase a bulk container of private label product like “purse size” hand sanitizer and resell individual units through sporting event snack shacks, corner markets, or their own small businesses. Should retailers be included in the definition of manufacturer in Section 69501.1(a)(41), they would be forced to begin tracking the intended use of covered product(s) from each of their own customers to ensure compliance with 69501.2(b)(1)(B) and (b)(2)(B).

Chemical Product Information – Section 69501.4

While we appreciate the need for the Department to seek information from responsible entities, verbiage used in the several areas of Section 69501.4 is of concern. Overall, timeframes for response are left entirely to the Department without any requirement that timeframes even be reasonable or achievable. This is especially

problematic given most data calls/information requests are contemplated via posting on a web site and/or through an electronic mailing list(s). Short of requiring 24-hour monitoring of a web site or electronic mailing list, it is reasonable to anticipate a lag between posting of information and actual receipt. At a minimum, a reasonableness standard should apply to all timelines established under Section 69501.4 and ideally timelines would include the qualifier of "not less than 30 business days".

Further, Section 69501.4(a)(4) appears to authorize the Department to require a responsible entity to undertake limitless research and data compilation mandates without even a reasonable basis to believe the information would be beneficial. A sweeping authority is included in Section 69501.4(a) to seek any information the Department feels, in its sole discretion and absent any restriction or limitation other than modest attempted protections for trade secrets, is necessary to implement the chapter. Applying that standard to existing information is challenging enough without the prospect of Department mandates to create entirely new bodies of documentation, data analysis or research.

In addition, Section 69501.4(c)(1)(C) is highly subjective and provides no indication of what actions would be necessary to demonstrate compliance or an inability to comply. Even if a particular manufacturer, importer or retailer were able to understand what actions were necessary during a specific data call/information request, that could change based on the individual preferences of Department staff over time. At a minimum, the Department should outline the steps required to meet the standard established under this section.

All of these challenges are compounded if the definition of "manufacturer" is not modified to correctly reflect the actual knowledge and capabilities of retailers. Retailers do not possess information that is proprietary to manufacturers yet would be required to produce that information at the request of the Department within timeframes established by the Department. In addition, they could be required to generate limitless "new" information about products they do not actually manufacture. And there is no indication what, if anything, the Department would accept to substantiate a retailer's statement that they do not have an ability to provide requested information.

Priority Products Prioritization Factors – Section 69503.2

While it is understandable for the Department to use market presence information to help prioritize products that will be subject to the Green Chemistry process, language contained in 69503.2(a)(3)(B) could force retailers to submit information to the Department that otherwise would be proprietary. The concern is compounded given the sweeping authority provided in Section 69501.4 to obtain existing and new data from responsible entities. The concern becomes more significant in light of the sweeping authority included in Section 69501.4(a) to seek any information the Department feels, in its sole discretion, is necessary to implement the chapter.

Specifically, Section 69503.2(1)(B)(1) discusses taking into consideration market presence information, statewide sales by volume, and statewide sales by unit of products. While this information likely should be taken into account, it is important that no grocery retailer be required to disclose publicly such information. It is unclear whether that kind of information could be considered "trade secrets" as defined in Civil Code section 3426.1(d) as it does not necessarily include a, "...formula, pattern, compilation, program, device, method, technique, or process". Yet the information is proprietary and if made public could provide competitors with information they otherwise would not have available to them.

At a minimum, the regulation should specify that market presence information, statewide sales volume data, and statewide sales by unit data will be either considered confidential by the Department or made publicly available only through aggregated, statewide figures rather than on the basis of any subset including company, retail format, etc... Generally, information regarding specific product sales data is not something grocery retailers distribute in a public way. That information could be used by competitors to target customer groups and gain market share.

Process to Evaluate Products Using the Prioritization Factors – 69503.3

Language contained in Section 69503.3(d) raises significant concerns about the ability of the Department to force safer alternatives on manufacturers even when no such alternative is feasible, functionally acceptable, or even legal. The proposed regulation notes that, “The Department *may, at its discretion*, consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible...” . The discretionary nature of consideration of that type of information, and no consideration of whether any existing alternative is legally allowable under other local, State, and/or Federal laws, rules and regulations leaves the door wide open to mandates for alternatives that are economically or functionally unacceptable or even legally problematic.

Language in the ISOR seems to imply that the Department would like the option to consider such issues as a means to help prioritize which products are evaluated (p. 99, line 19 et seq). At a minimum, language in the regulation should be modified to *require* the Department to take into consideration the availability, economic feasibility, and functionality of alternatives along with legal issues around their use.

Priority Product Notifications – Section 69503.7

A significant timing issue appears to exist with regard to retailers and the requirement to provide the Department with certain information about priority products. Section 69503.7(a)(1), (a)(2), and (a)(3) require, “... each responsible entity...” to submit detailed information to the Department about priority products and contact information for the person responsible for complying with the requirements of the regulation unless other specified notices have been submitted. In many cases, a grocery retailer will not have that information as they do not generally manufacture products and therefore will not generally know what priority products they sell until information on the brand/product name(s) are publicly available. This issue is compounded if grocery retailers are in fact considered manufacturers of products they do not themselves manufacture.

For example, if Product Y containing Chemical X is listed as a priority product, a grocery retailer will know whether they carry a version of Product Y but they will not generally know whether it contains Chemical X until a list of brand/product name(s) is available. Even when contacting the manufacturer of Product Y, a grocery retailer may not receive a response within the required timeline for notifying the Department.

In addition, at this early stage of the process, a grocery retailer would have no idea whether a manufacturer or supplier intends to comply and if so, what person will be responsible for ensuring compliance. They also would have no way to determine whether they themselves need to assign a person to ensure compliance with the regulation. For example, even if a grocery retailer were able to determine that the Product Y they carry contains Chemical X, they will not know whether the manufacturer or supplier of Product Y intends to comply until and unless information on the brand/product name is made public or that product appears on the Failure to Comply List outlined in Section 69501.2.

Regulatory Response Selection Principles – Section 69506

In selecting any required regulatory responses after product evaluation, Section 69506(c) *authorizes* the Department to consider several factors including, “...likely actual effectiveness”, “...relative cost-effectiveness”, “...administrative and other burdens”, “...unique or additional burdens”, and “...ease and efficacy of enforcement.” Rather than being interesting issues that may or may not need to be considered, it seems that these are all critical components to determining what regulatory response to impose. Consideration of these factors should be mandatory for the Department, not left to bureaucratic whim.

Absent a mandate to weigh these considerations, it is entirely feasible that the Department could select an ineffective, expensive, burdensome, unenforceable regulatory response. That would not serve the interests of California consumers, regulators or grocery retailers. For example, after testing of Product Y the Department could learn of two different regulatory responses. Response A would double the cost of the product, result in a 10% reduction in exposure and require ten additional Department staff to enforce. Response B would increase product cost by 15%, reduce exposures by 85% and require no additional Department staff to enforce. Under the proposed verbiage of Section 69506(c), California could very well end up with Response A – the much less effective and more costly response.

It makes little sense to craft a regulation that allows for that outcome, yet that is precisely what the proposed regulation would allow. A regulatory response could be mandated even when there is no capacity on the part of responsible entities to comply or when it is demonstrated that end-users have no ability to act upon the response.

Applicability and Determination Process – Section 69506.1

As outlined in the ISOR, this Section is designed to provide affected entities and interested parties with an opportunity to review and comment on regulatory response options prior to final determination of required responses (p. 157, line 27 et seq). Unfortunately, the proposal fails in some regards to make that opportunity meaningful to those providing comment and renders the process less than useful to the Department.

Specifically, Section 69506.1(c) states only that the Department “...*may* respond to *some or all* public comments received.” If the objective is to provide meaningful input, the Department should be required to respond to all comments. Otherwise, how are affected/interested parties to know that their comments were reviewed let alone considered by the Department? Comments could simply be accepted and filed away without review, robbing the public of meaningful participation and robbing the Department of critical and important information regarding proposed responses.

For example, if a regulatory response were proposed that would be significantly burdensome for consumers, manufacturers or retailers yet comments submitted to that effect were not read and responded to, the Department could impose a regulatory response that is inappropriate or ineffective. Dissent or critique often provides the best opportunity for improvement and to allow the Department to arbitrarily dismiss all or some comments received by affected/interested parties is counterproductive.

Product Information for Consumers – Section 69506.4

Significant issues exist with regard to Section 69506.4(b)(2)(B), which authorizes specified product information to be distributed to consumers via point of sale methods that include, “Posting the information in a prominent place at the point of retail display.” This should not be an option that is forced on grocery retailers unless they willingly agree to engage in such consumer education.

Shelf space in grocery retail is extremely limited with significant requirements for information display already in place. They include information on pricing, product size/weight, product qualification under certain food assistance programs, etc... In addition, many grocery retailers attempt to provide consumers with non-mandatory health information such as noting which products are gluten free, organic, or low sodium, posting Nu Val scores, etc... It is entirely unworkable for the Department to mandate additional required disclosures absent a grocery retailer’s agreement to participate in that kind of consumer education.

The problem is compounded when you take into consideration that a number of different manufacturers may exist for a given product, each with different verbiage, color scheme, presentation, etc... for the information. For example, if Product Y containing Chemical X is manufactured and sold under six different brand names, a grocery retailer could be forced to install and maintain six separate signs/banners/shelf tags in a prominent manner at the point of retail display. One can easily envision grocery aisles littered with banners repeating the same information over and over about products – blocking consumer access to products, impeding pathways down aisles, and making it challenging for consumers to sort out issues like product price and value.

And there is no indication what “prominent” means. The ISOR indicates that lack of clarity is meant to foster flexibility (p. 161, line 36 et seq) but in reality absent clarity on whether other legal requirements for posting of information take precedence, it is unclear what would be considered “prominent”. Given the volume of information required, the notices under this regulation could well dwarf pricing, product size/weight and other information that is legally required. That could, in turn, create peril for grocery retailers with regard to whether they are meeting their obligations to adequately inform the shopping public about those issues.

Use Restrictions on Chemical(s) of Concern and Consumer Products – Section 69506.5

Similarly, concerns exist with regard to the regulation as proposed for use restrictions on products. Several restrictions could create competitive and operational challenges for grocery retailers. Specifically:

Section 69506.5(b), which restricts settings in which a product may be sold or used, should be clarified to ensure that no particular grocery retail format is given a competitive advantage by being allowed to sell products a competitor is not based solely on their business model. For instance, the regulation appears to leave open the option of saying that certain products may only be sold in grocery retail outlets of a specified square footage, or those choosing to display products in a certain manner, or those that refrain from selling other related products.

Section 69506(d), which restricts who may purchase and/or use a product should be specific that a grocery retailer is not penalized for inadvertent or occasional sales that may occur to unauthorized populations. Grocery retailers should be given notice of any alleged sales violation and afforded an opportunity to engage in retraining of employees when human error is involved before penalties apply. In addition, it should be made

clear that grocery retailers are not responsible for monitoring end use of a product. There is no way for a grocery retailer to ensure that a product sold to an individual is in fact used by that individual and not provided to a third party for use in violation of any use restrictions. Grocery retailers cannot and should not be held responsible beyond the point of sale.

Section 69506(e), which involves training of purchasers or end users, is frankly impossible for grocery retailers to accommodate and this should not be a requirement that applies to them. It is hard to envision how a grocery retailer would conduct training sessions for purchasers. If this were a requirement prior to purchase, would a grocery retailer need to lock up regulated products and force customers through training? Or perhaps station an employee next to each covered product and train purchasers as they pull the item off the shelf? Should a grocery retailer have a clerk or designated trainer spend time at the check stand educating a purchaser while the line grows (and grows impatient) behind them? Or perhaps force customers to stop by customer service for training prior to exiting the store? This provision is simply unworkable as a mandate and should not be contemplated at retail.

Section 69506(f) contains sweeping authority for the Department to impose, "...any other use restriction..." without regard to feasibility, cost, effectiveness, etc... While it is understandable that the Department would want to maintain latitude with regard to future technologies and market evolution, as intimated in the ISOR (p. 162, lines 5 et seq), some parameters should be included that ensure any future use restrictions are, at a minimum, feasible, affordable, and effective.

Product Sales Prohibition – Section 69506.6

Significant concerns exist with several areas of this Section. Generally, there are several modifications required in compliance timelines provided in the Section. Specifically, in Section 69506.6(c)(1), (d)(4), and (e)(2) a qualifier, "...unless the notification specifies a shorter period of time..." (or substantially similar verbiage) is included. This leaves open the possibility that unworkable timeframes could be provided especially in light of the fact that the shorter period of time has no qualifiers of its own relating to complexity, cost, or feasibility.

Under the language currently proposed, it is not unrealistic to expect companies will receive notifications with much shorter timelines given the Department's understandable desire to encourage prompt action on the part of the regulated community. However, providing timelines that are unworkable or impractical for responsible parties could result in supply chain disruptions and product unavailability. The Department should utilize language that timelines are, "...no longer than..." as proposed in Section 69506.6(e)(3) consistently throughout. Shorter timelines could be authorized if exigent circumstances exist and can be articulated by the Department in the notification.

Concerns also exist with regard to the process articulated in Section 69506.6(d) to remove products from the stream of commerce even when, "...there are no currently identified safer alternatives that are both functionally acceptable and technically and economically feasible." While there may be isolated incidents when a product is considered so dangerous that it must be removed from the stream of commerce absent acceptable alternatives, it is difficult to understand why existing consumer protection and public health regulators would not already have authority to do so – and on much shorter timelines than those provided in this Section.

Even if one accepts the premise that the Green Chemistry process is going to somehow reveal public health and environmental impacts so severe they necessitate removal of products where no alternatives exist, the language in Section 69506.6(d)(2)(A) and (2)(B) is overly restrictive. The only impacts to be considered are public health and environmental impact. Why are those two categories of impacts prioritized? Why are other impacts not allowable for consideration?

End-of-Life Management Requirements – Section 69506.8

There are significant, overarching concerns that Section 69056.8 is drafted in a manner that exceeds the explicit authority provided in Health & Safety Code (HSC) Section 25253. Specifically, HSC Section 25253(b)(7) reads, "Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product". Yet in the proposed regulation, Section 69506.8 repeatedly refers to requirements for "a responsible entity" or "the responsible entity", which according to Section 69501.1(54) could include not only manufacturers but also importers or retailers. Inclusion of additional parties beyond those outlined in statute (ie beyond manufacturers) is not authorized by statute and therefore impermissible. In addition, several other concerns exist with the section.

Section 69506.8(a)(2) notes that a responsible entity shall, "...fund, establish and maintain an end-of-life management program..." when again, HSC Section 25253(b)(7) is explicit in noting that manufacturers are to be assigned responsibility for end-of-life management, not importers or retailers.

Section 69506.8(a)(2)(A) requires the development and maintenance of a comprehensive product stewardship with specified components. One of those components, contained in Section 69506.8(a)(2)(A)(3) includes, "...roles and responsibilities for manufacturers, importers, retailers, consumers, and government....and identification of retailers who have agreed to participate in the program." Unfortunately, this language appears to leave the door open for a manufacturer to create a plan that imposes responsibilities on importers and grocery retailers without the advice and most importantly consent of those parties. In addition, the ISOR references a need to, "...hold the various parties accountable and ensure the success of the product stewardship plan." (p. 168, line 45, p. 169, lines 1 et seq). Again, the only entity HSC Section 25253(b)(7) assigns responsibility for end-of-life management is manufacturers. Other responsible entities should only be assigned roles and responsibilities if they consent.

As currently drafted, Section 69506.8(a)(2)(A) would allow a manufacturer to submit a stewardship plan that calls for grocery retailers to accept hazardous waste for in-store recycling or disposal purposes – even though grocery retailers may be unable to do so without violating the stringent requirements for licensed food facilities. In that instance, the manufacturer would be not only be circumventing the requirements of HSC Section 25253(b)(7) but in addition proposing a plan that will ultimately be unsuccessful. It is imperative that if responsibilities are contemplated beyond those authorized by HSC Section 25253(b)(7), i.e. beyond manufacturers, that importer and/or retailer participation be entirely voluntary.

Similar concerns exist with Section 69506.8(a)(2)(A)(7)(a) and (2)(A)(7)(b), which covers financial guarantees. Section 69506.8(a)(7)(a) requires the "responsible entity" to provide a financial guarantee to sustain any end-of-life management program. Section 69506.8(a)(2)(A)(7)(b) defines such guarantee as, "...any mechanism...to ensure that adequate funding is available...". Once again, this proposed verbiage assigns responsibilities to entities beyond those outlined in HSC Section 25253(b)(7) and does so in an inappropriate way. A manufacturer could submit a plan with a financial guarantee mechanism that requires importers or retailers to

collect fees, pay fees, or otherwise financially support the end-of-life management program without the consent or even input of those parties. This is unacceptable and any assignment of duties beyond those required in HSC Section 25253(b)(7) must be entirely voluntary on the part of importers and retailers.

Likewise, Section 69506.8(a)(2)(A)(10) notes inclusion of public education, outreach and communication plans. Participation in those efforts by importers and retailers must be entirely voluntary based on HSC Section 25253(b)(7). Otherwise, a plan could contain requirements for importers or grocery retailers to conduct trainings, produce educational materials, fund and/or produce public information announcements, etc... without their consent or even input.

Section 69506.8(a)(2)(B) is problematic as well. We are pleased that the proposed regulation does at least require, "...consultation with retailers and owners/operators of prospective collection sites..." but have concerns that Section 69506.8(a)(2)(B)(1) and (B)(2) provide for collection mechanisms *and/or* compensation to retailers or others agreeing to administer or participate in collection. Given HSC Section 25253(b)(7) requires manufacturers to manage products at the end of their useful life, there should be no requirement that retailers participate in collection programs and an absolute ability of retailers to obtain reimbursement for any voluntary participation in collection programs. Those should not be issues for manufacturers to decide. As drafted, the regulation would allow a manufacturer to require in-store collection of hazardous waste and refuse to reimburse a grocery retailer for their expenses in dealing with those substances inside a licensed food facility. A significant body of law exists regarding handling of hazardous wastes like punctured bleach bottles and pesticides at grocery retailers and adding to those burdens should be a retailer option, not manufacturer option. Furthermore, retailers should be reimbursed for financial burdens associated with participation in a collection program.

Section 69506.8(c) should be clarified to address issues noted above with regard to any alternative end-of-life management plan submitted by a manufacturer. Participation on the part of entities beyond those outlined in HSC Section 25253(b)(7) should be entirely voluntary and reimbursable.

Regulatory Response Selection and Re-Evaluation – Section 69506.10

It is unclear what situations are contemplated in Section 69506.10(a). The sweeping authority provided in the proposed regulation merely outlines, "...situations other than those specified in those sections." HSC Section 25253(a)(1) and (2) authorize regulations to establish a process for evaluating chemicals of concern to determine how best to limit exposure, while HSC Section 25253(b) authorizes regulations to establish a process that includes evaluation of those chemicals and regulatory responses. It is unclear where regulatory action or intervention beyond that is established in the statute. Latitude is authorized with regard to both life cycle assessment tools and regulatory responses but authority to apply those processes and responses to additional situations is unclear. At a minimum, the regulation should be modified to clearly outline the authority to reach beyond the Green Chemistry process established in the Health & Safety Code and then to set parameters for such additional reach.

Further, Section 69506.10(b) should be clarified to provide a framework for frequency of re-evaluations. As drafted, it is possible for the Department to review immediately upon completion of the process outlined in the regulation. That review contemplates a new Alternatives Analysis and reports setting up the potential for an unending process that places responsible entities on a costly, cumbersome regulatory treadmill.

Regulatory Reponses Report and Notifications – Section 69506.12

The due date for compliance in Section 69506.12(b)(4) to be communicated in the regulatory response report and notifications should be no sooner than 180 days from the date of the notice. In addition, consideration of factors outlined in Section 69506(c)(1)-(5) should be a requirement in determining the due date. If these minor issues are not explicitly addressed, it is possible that a notice under Section 69506.12 would contain a due date that varies from compliance dates established elsewhere in the development and approval of mandated regulatory responses.

Dispute Resolution – Section 69507

Significant concerns exist with the proposed regulation in the area of dispute resolution. Language contained in 69507(b) notes that, "If the responsible entity fails to follow the procedures specified in this article for disputes subject to this article, it waives its right to further contest the disputed issues administratively." As noted in the ISOR (p. 177, lines 20 et seq), this language sets up a scenario where a responsible entity could make a technical error in the process or procedures required by the Department and via that technical error would be deprived of not only administrative but also judicial review of a dispute. This seems to be heavy-handed at best and an arbitrary denial of due process at worst. Any authority to limit or eliminate the right to resolve disputes is not apparent in a reading of HSC Sections 25251, 25252, 25252.5, and 25253.

At a minimum, language should be modified to allow parties to seek redress in the judicial system if failure to comply with administrative processes is the result of issues including but not limited to technical errors, inadvertent action or inaction, or circumstances beyond the control of the responsible entity, etc... While ideally the Department would proceed on this issue with a much more accommodating approach given the significance of decisions it is making with regard to consumer products in California, if there is not a willingness to do that, responsible entities should be allowed to seek redress in the Courts that they are unable to obtain administratively.

Concerns also exist with the exemptions contained in Section 69507(c) noting that decisions regarding the Chemicals of Concern Identification Process, the Petition Process for Identification and Prioritization of Chemicals and Products, and Trade Secrets are not subject to dispute resolution. Again, any authority to limit or eliminate the right to resolve disputes is not apparent in a reading of HSC Sections 25251, 25252, 25252.5, and 25253.

Along the same vein, Section 69507.5 outlines requirements for the contents of any requests for review. Specifically, the proposed language and clarification contained in the ISOR (p. 179, lines 42 et seq) limits requests for review to only those circumstances where a showing can be made that the Department based a decision on bona fide errors in facts, assumptions, approaches, or conclusions of law or circumstances where the Department decides, "...in its own discretion..." that it should reconsider a policy judgment. It is unclear where authority to limit or eliminate the right to request review of decisions exists in HSC Sections 25251, 25252, 25252.5, and 25253.

Ms. Krysia Von Burg
October 11, 2012
Page 11 of 11

I thank you in advance for consideration of these comments. While other challenges exist with the proposed regulation, these are issues we felt were critical to address. As noted, many hinge on the Department's decision to include parties other than product manufacturers in its definition of manufacturer. Unfortunately, that decision places those other parties, including grocery retailers, in a very perilous position. They do not have access to product formulations and are not in a position to make decisions or commitments on behalf of manufacturers with regard to formulations or regulatory responses. Yet under the proposed regulation, grocery retailers would incur significant responsibilities to file reports, conduct tests, make decisions with regard to reformulation options, and discuss the feasibility of regulatory responses. All without access to information like product formulations that is proprietary to manufacturers.

Similarly, the proposal contains several mechanisms for manufacturers or others to mandate actions and activities on the part of importers and grocery retailers in the context of regulatory responses and end-of-life management. Those mechanisms are in some cases not authorized in the Health & Safety Code, and in all cases inappropriate as mandates. Importers and retailers should participate in regulatory responses only to the extent it is feasible and in end-of-life management activities only to the extent that they are willing and able to do so. Grocery retailers, in particular, have significant additional regulation with regard to handling of hazardous, and all, materials inside their licensed food facilities. The proposal as drafted creates significant jeopardy for grocery retailers who could be forced into a position of choosing whether they violate the mandates of the Department with regard to regulatory responses or end-of-life management, or violate food safety laws or laws relating to information they are otherwise required to provide consumers.

Should you have any questions about these comments, please do not hesitate to contact me. And thank you, again, for consideration of noted concerns.

Thank you,



Keri Askew Bailey
Vice President, Government Relations
California Grocers Association

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of
Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-
0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the California Healthcare Institute (CHI), I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

CHI was founded in 1993 and represents California's premier biotechnology, pharmaceutical, diagnostics and device companies, venture capital firms, public and private universities and academic research institutions. California is home to over 2,300 biomedical companies, the largest number of biomedical companies of any state in the country. California's biomedical companies generated a total estimated annual revenue of \$115.4 billion in 2010. The biomedical industry directly employs approximately 270,000 people in California.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system. We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly.

Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the

regulation would address the practical problems raised by the scope and complexity of the draft.

Below are several of CHI's top concerns with the proposed regulation. We highlight these but note that there are other areas which remain of concern.

- The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).
- The Department has reserved for itself significant latitude to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on **exposure** and **hazard**, and it must avoid duplication and conflicting regulatory requirements.
 - DTSC's draft regulation proposes to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints

that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** The priority should be on the potential ability to create harm, not on speculative concerns or minor impacts. As an example, the USEPA identified a work plan of 83 chemicals of concern for further assessment and identified seven of these chemicals for risk assessment in 2012.

- GCA supports this two step approach, i.e., “chemicals under consideration” and “chemicals of concern.” In this regard, we concur with GCA’s recommendation that DTSC begin by identifying their list of 1200+ chemicals of “Chemicals Under Consideration.” DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***
- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. However, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.
- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.
- The regulation should expressly exempt products that are already subject to a comprehensive regulatory scheme that would prevent or limit a manufacturer’s ability to respond to DTSC’s requirements. For example, should DTSC determine that a manufacturer of an over-the-counter drug must substitute ingredients or change a product’s labeling, it could cause the product to be misbranded or adulterated under the Federal Food Drug & Cosmetic Act.
- Contrary to DTSC’s assertions, the regulation will have a significant effect on business in California. According to an October 8 report from the California

Foundation for Commerce & Education, the regulation could potentially cost California businesses and consumers over \$170 billion in the first 25 years of implementation. Total net costs to California businesses and consumers in the first 25 years of implementation could approach \$150 billion. Additionally, the regulation could directly affect 123,000 jobs in California at the peak of implementation. We urge DTSC to undergo a thorough, meaningful analysis of the potential economic impact of the regulation.

We appreciate your consideration of our concerns. For further information, please contact me at Hernandez@chi.org or 916-443-5576.

Sincerely,

A handwritten signature in cursive script that reads "Consuelo Hernandez". The signature is written in black ink on a white background.

Consuelo Hernandez
Vice-President – State Government Affairs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



October 11, 2012

Debbie Raphael, Director
Kryisia Von Burg, Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Safer Consumer Products Regulations
DTSC Reference Number: R-2011-02

Dear Director Debbie Raphael and Department of Toxic Substances Control:

The California Healthy Nail Salon Collaborative is writing to comment on DTSC's draft regulations to implement a Safer Consumer Products (SCP) program in response to AB 1879.

The California Healthy Nail Salon Collaborative (Collaborative) focuses on the health, safety and rights of nail salon and cosmetology workers and owners. The Collaborative has over 30 members, comprising environmental justice, reproductive justice, and public health organizations and advocates, researchers, government agency allies and others.

The Nail Salon Industry.

In the US, in the last decade, the number of nail technicians has jumped 374% to more than 380,000 nationwide, with women making up to 96% of the industry's workforce. The majority of nail salon workers are women of color, an estimated 42% nation-wide are Asian immigrants, and most are of reproductive age. One in five manicurists work in California, where up to 80% are Vietnamese women. Many salon workers speak limited English and lack an understanding of and access to regulatory, legal and health care systems. Most tend to earn less than \$18,200 a year, lack health insurance and work in conditions that can be hazardous to their health.

Salon products contain many harmful chemicals.

On a daily basis, salon workers handle solvents, glues, polishes, dyes and other beauty care products containing a multitude of chemicals known or suspected to cause cancer, allergies, respiratory, neurological and reproductive harm. Women working in salons are increasingly reporting acute health concerns such as headaches, dizziness, rashes and breathing difficulties in addition to more serious/chronic problems such as miscarriages, birth defects, cancers and respiratory illnesses. Published studies that have measured the level of air contaminants in beauty salons suggest that even when exposures are well below current occupational exposure standards, workers still experience related health problems.^{1 2}

While acute impacts in salons have been well-documented, little research has been conducted on the long-term, chronic health impacts resulting from occupational exposures. New studies provide reason for concern, correlating health problems with daily exposure to chemicals in salon products by this worker population. Several studies have shown that nail salon workers have higher - in fact 2-fold higher - levels of di-*n*-butyl phthalate (DBP), a reproductive and developmental toxicant, than the general population.^{3 4} Another study found that beauticians are likely to have significant exposure to solvents that are linked to birth defects.⁵ Other studies have found cosmetologists are at a higher risk for having spontaneous abortions and low birth weight babies.^{6 7}

Three chemicals of particular concern in nail salon products are toluene, formaldehyde and DBP (the "toxic trio"). Toluene creates a smooth finish across the nail and keeps the pigment from separating in the bottle. It is a common volatile solvent that can impact the central nervous system, cause irritation of the eyes, throat and lungs, and is a possible reproductive toxin. Formaldehyde, a nail-hardening agent, is also a volatile chemical that evaporates into the air of salons and is known to cause cancer. Exposure to DBP, added to polishes to provide flexibility and a moisturizing sheen, can affect thyroid function. It has been linked to reproductive harm, including decreased sperm count in adult men. Products used in salons contain a myriad of other compounds that are known to be harmful or have no toxicological data at all.

¹ Labrèche, F, et al., "Characterization of Chemical Exposures in Hairdressing Salons," *Applied Occupational Health and Environment*, 2003; 18: 1014-1021.

² Industrial Hygiene Assessment of Toluene and Formaldehyde Concentrations in California Nail and Full Service Salons, Clayton Project, project no. 800-97276.00, Clayton Environmental Consultants, Santa Ana, CA, March 16, 1999.

³ Hines J, Cynthia et al. "Urinary Phthalate Metabolite Concentrations among Workers in Selected Industries: A Pilot Biomonitoring Study." *The Annals of Occupational Hygiene*. (2009); 53(1):1-17

⁴ Kwapniewski, Rachel et al. Occupational Exposure to Dibutyl Phthalate Among Manicurists." *Journal of Occupational and Environmental Medicine* (2008); Vol. 50, No.6.

⁵ Garlantezec, Monfort, Cordier. "Maternal occupational exposure to solvents and congenital malformations: a prospective study in the general population." *Occup. Environ. Med.* (2009); 66: 456-463

⁶ John, EM, Savitz D, Shy C. "Spontaneous abortions among cosmetologists." *Epidemiology*. (1994) Mar; 5(2): 147-155

⁷ Herdt-Losavio ML. "The risk of having a low birth weight or preterm infant among cosmetologists in New York State." *Maternal Child Health Journal*. (2009) Jan; 13(1):90-7.

There is little statutory or regulatory oversight of salon products and the chemicals they contain.

Despite documented occupational exposures, state and federal regulatory oversight of chemicals used in salons is limited and ineffective. While the Food and Drug Administration is authorized to regulate cosmetics, it has limited authority to actually do so. It is currently legal for cosmetics manufacturers to use virtually unlimited amounts of any chemical in beauty products, including chemicals linked to cancer, reproductive and developmental harm, and hormone disruption, with no premarket safety assessment. Of the more than 10,000 chemicals used in beauty products, 89% have not been tested independently for their safety or impacts on human health.

This vacuum in regulatory protection creates a context where manufacturers have no incentive to reformulate their products or substitute harmful chemicals with safer ones. The burden created by industry's failure to take upstream responsibility for the safety of chemicals used in salon products falls unfairly upon salon workers and owners and often translates into occupational exposures that can lead to poor health outcomes.

The Safer Consumer Products regulations should fully integrate consideration of worker health.

We believe that the AB 1879 statutory and regulatory scheme can fill the statutory and regulatory void referred to above. The Collaborative has reviewed the informal draft regulations with an eye toward their impact on its constituency, largely low-wage immigrant women workers of reproductive age. We applaud many aspects of the draft regulations, including the intention to regulate chemicals and products by focusing first on intrinsic hazard traits of chemicals rather than relying only on risk assessment.

We also believe it is essential that consideration of occupational health be fully integrated into the regulations due to workers experiencing chemical exposures that are generally of higher levels and/or longer duration than experienced by the general public. Additionally, worker exposures at all stages of a product's life cycle should be considered, whether at the manufacture, transfer, use, disposal or other stage. Compared to the last round of informal draft regulations, the current formal draft regulations show marked improvement, but there is still room for improvement.

Below are our comments and recommendations regarding these and other issues in the draft regulations released on July 27, 2012. We ask that you consider them as you move forward with this important program.

**Workers are appropriately included
in the definition of “sensitive sub-populations” .**

§ 69501.1(a)(58), page 13 lines 19-25

The Collaborative supports the inclusion of language in the definition that identifies workers as a sensitive sub-population when they experience greater chemical exposures due to the nature of their occupation. It recognizes that occupational hazards often lead to greater and longer exposures than those encountered in other settings; for example, a woman manicuring her nails at home versus a nail salon worker providing a dozen or more manicures per day.

The wording in this section could and should be improved, however because workers face increased hazards not only because of the “nature of their occupation” but also because of the specific tasks or activities they perform at work. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. It’s what they actually do that matters.

Revise as follows: "Sensitive populations" also include persons at greater risk of adverse health effects when exposed to chemicals, because they are either individuals with a history of serious illness or greater exposures, or workers with greater exposures than the general population, due to the nature of their occupation and specific duties.

**The definition of “sensitive sub-populations”
should be expanded to include women of reproductive age.**

We also believe women of reproductive age, who are predominant among nail salon workers, should be added as a sensitive sub-population. The first weeks of gestation are a time of rapid development for the fetus and therefore also a time of critical vulnerability to harm. Consequently, many hazards to normal development threaten the fetus *in utero* early in pregnancy including before a woman may know she is pregnant.

**The draft regulations rely too often on an inadequate approach
of simply controlling or containing chemical exposures rather than preventing them.**

We recognize that exposure data will be considered in the SCP implementation, but if a substance is dangerous, this is reason enough to act to reduce or eliminate its use—not just control or contain it. The inadequacy of this approach can be seen in the occupational setting where “containment” and limit standards are often out of date and not sufficiently protective.

Moreover, containment fails to drive the development and use of safer, less toxic chemicals, which is one of the overarching goals of both the SCP regulations and California's broader Green Chemistry Initiative.

§ 69506.7(b), page 57

We believe that reasons for DTSC to impose control measures are in fact reasons for responsible entities to completely eradicate the use of their Chemical(s) of Concern by seeking other and safer alternatives. Consequently, it should be stated clearly in this section that such requirements would be imposed or allowed as only interim actions to protect public and/or environmental health until such safer alternatives can be developed.

§ 69506 (b), page 52, lines 10-14

The Collaborative strongly supports the language in this section which says that the Department will “give preference to regulatory responses providing the greatest level of inherent protection....” This section makes it clear that the ultimate goal of these regulations is the actual elimination of toxic chemicals.

§ 69501 (a), page 4, lines 8-12

Revise as follows: This chapter specifies the process for identifying chemicals as Chemicals of Concern, and the process for prioritizing consumer products containing Chemicals of Concern and identifying alternatives to consider for Priority Products to determine how best to reduce the use of toxic chemicals, or the level of adverse impacts posed by the Chemical of Concern in the product.

§ 69501.1(a)(11)(D), page 7, line 24

Revise as follows: If Removal, Reformulation, or Redesign is not feasible, another change to a Priority Product or a manufacturing process that reduces the adverse public health and/or environmental impacts or exposure associated with the Chemical(s) of Concern in the Priority Product.

§ 69505.3 (b)(2)(A)1, page 41, lines 30-35

Revise as follows: In addition to any alternative identified under paragraph (1)(C)2., the responsible entity shall identify alternatives that meet the definition of “alternative” under Section 69501(a)(11) and meet the requirements identified under paragraph (1)(A) for the Priority Product, and that eliminate or reduce the concentration of the Chemical(s) of Concern in the Priority Product. If a

responsible entity concludes that eliminating or reducing the concentration of the Chemical(s) of Concern in the Priority Product is not immediately feasible, they should reduce or restrict the potential for release of the Chemical(s) of Concern, leading to human or environmental exposures, as an interim action until a safer alternative is developed.

Language Access

Any information provided either as hard copy written materials or on the website should be translated into at least the following languages: Spanish, Vietnamese, Chinese, and Korean. Exceptions to this might be such technical and scientific language as chemical names

Definitions

§ 69501 (b)(3), page 4, lines 22:

Delete: Workers in California experience exposures related to the manufacture, storage, or transport of products in California regardless of where those products are eventually sold. Workers and fenceline communities are members of the public who are entitled to equal protection from harmful substances. Additionally, to exclude these products ignores life-cycle thinking that is one of the hallmarks of this paradigm shift in regulating chemicals.

§ 69501.1(a)(6), page 6, lines 4-5

We support the following existing language: "Public health includes occupational health."

§ 69501.1 (a)(22)(A), page 8, line 32

Revise: DTSC should ensure that the definition of "Consumer Product" makes clear that chemicals and products used in the workplace, including bulk purchases, are included. Add a subsection 4 to read: Chemicals and products used in the workplace, including bulk purchases.

§ 69501.1(a)(53)(A)2, page 12, lines 14-15

We support the following language regarding monitoring data especially to places of employment: "Present in, or released from, products used in or present in the home or places of employment."

§ 69505.5 (f)(2)(B)

This section requires responsible entities to describe how safeguards provided by other federal or state regulations were considered in their Alternatives Assessments (AA). DTSC should add language here to ensure that AAs do not rely on outdated and inadequate occupational exposure limits in the development of a safer alternative chemical or product.

A comprehensive Chemicals of Concern list including those with hazard traits that greatly impact workers is critical to the SCP program's success.

A large Chemicals of Concern (CoC) list will support, encourage, and stimulate efforts by innovative entrepreneurs and businesses to voluntarily conduct research and develop safer cosmetics and other consumer products before regulation compels them to do so. This will create jobs for California's green economic development. The size of this list will, as DTSC intends, help reduce the problem of regrettable substitutions. A large CoC list will enable DTSC to use scarce resources for other important program activities.

The Collaborative believes retaining the term "chemicals of concern" in the regulations is appropriate and legally required because the language of AB 1879 explicitly requires DTSC to identify "chemicals of concern" in Section 25252 (a) -- not "chemicals under consideration."

DTSC should specify that when any of the lists it relies on is updated, the updated list becomes the version that DTSC uses for its own CoC list.

DTSC should ensure that all hazard traits identified by Office of Environmental Health Hazard Assessment (OEHHA) are captured in its CoC list, including neuro-developmental hazard traits.

While the current chemical of concern list is a good start, we believe it needs to be expanded to be as protective as possible for nail salon and other workers and consumers. For instance, asthmagens, respiratory sensitizers, skin irritants/sensitizers such as acetone, ethyl methacrylate, nitrocellulose, alumina, tosylamide formaldehyde resin, and quarternary compounds to name a few, should be added. These and other chemicals can have long term effects on nail and hair salon workers who work every day with currently under-regulated products such as hair straighteners and nail products.

OEHHA lists these hazard traits already (e.g., Chapter 54, s. 69403.16 Respiratory Toxicity) and there are lists available from North America and Europe. The Globally Harmonized System of Classification and Labeling of Chemicals (GHS) also includes these hazard traits, which the US federal Hazard Communication Standard will require to be considered on "safety data sheets" in the next few years.

For lists of asthmagens and other sensitizers, see:

- <http://www.cdc.gov/niosh/topics/skin> (NIOSH information about skin irritants and sensitizers);
- <http://www.aoecdata.org/ExpCodeLookup.aspx> (Association of Occupational and Environmental Clinics -- AOEC);
- <http://esis.jrc.ec.europa.eu/index.php?PGM=cla> (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
- http://www.cleanproduction.org/library/greenScreenv1-2/Green_Screen_v1-2_Supporting_Lists.pdf

DTSC actions, as well as innovation, will be hampered by dependence on only information and alternatives that are already available.

§§ 69501.4(a)(3), page17,lines39-41; 69501.4(a)(4),page18,lines 1-3; 69501.4(b), page 18,lines 4-5.

DTSC should exert its call-in authority under AB 1879 to require – not just request -- the generation of new health and environmental impact data and the development of new safer alternative chemicals and products. DTSC should exercise this authority as early as possible in the program’s implementation.

Revise: Replace “request” with “require.”

§§ 69502.2(b)(3) and(4), pages 23-24

The draft regulations give preference to information that is already “available.” Prioritization and other decisions are dependent on the current availability of safer alternatives. This sends the wrong signal to the marketplace and in fact runs counter to the goals of the SCP program which is to promote the development of new and safer alternatives -- not exacerbate an already existing data gap.

These subsections are examples where, in considering additions to the CoC list, DTSC could require responsible entities to provide or produce the data that is needed to fill in any gaps in understanding the health effects of a chemical, instead of merely considering “the availability of reliable information to substantiate the potential adverse impacts and exposures.” This would reverse the burden of proof and bring more information forward sooner.

§ 69505.4(a)(2), page 43, lines 1 and 2

Delete “available” in both lines.

§ 69506.2(a) and (b), 53, lines 29-42

The Collaborative strongly supports the language in these sections that gives DTSC authority to require the provision or development of needed additional information. This information would be even more useful earlier in the process.

**The regulations should create a mechanism
for flagging understudied chemicals.**

The Collaborative believes that chemicals for which there is little or no information demonstrating whether they are safe should be considered CoCs under AB 1879, giving DTSC the authority to require providing or developing information in order to properly assess these chemicals.

In the absence of a minimum data requirement, the regulations should at the very least create a mechanism to identify these chemicals – a “yellow flag” that sends a message to the market and the public that they are under-studied and not necessarily safe.

Product Feasibility and Acceptability

§69501.1(a)(31), page 9, lines 32-36

Using “acceptability” as a factor in determining feasibility and functionality creates a loophole with great potential for abuse by manufacturers. We suggest the following changes.

“Functionally acceptable” should be replaced with “functionally equivalent or similar.”

The following phrase in (B) “....consumers can be reasonably anticipated to accept the product in the marketplace,” is too vague and is unknowable.

Revise (B) to read as follows: The product performs the functions of the original product sufficiently well that the product’s goals are reasonably well attained.

§69501.1(a)(59)(A) (B), page 13, lines 27-32

In (A), replace “...and to meet consumer demand after an appropriate phase-in period” with “and be functionally equivalent or similar.”

§69505.4(a)(2), page 43

This section gives no guidance as to how the factors in (2)(A)(B) and (C) are to be weighed. It seems to say that economic impacts are given equal weight as are given health impacts, and can possibly even trump. Subsection (2), last sentence, should be revised as follows:

The factors identified in subparagraphs (B) and (C) shall be considered relevant for all comparisons of the Priority Product and the alternatives but greater weight shall be placed on the factors set forth in (A).

69505.4(a)(2)(C), page 43

Costs to public and private institutions and society at large must be considered. Therefore, we recommend the following:

Add new factor under (C) to read as follows: Public costs including health care due to injury or illness, job loss, and other costs borne by society at large.

Delete “marketing costs” as there will be a huge range in level of marketing among responsible entities such as “boutique” nail polish and other salon product manufacturers . This will tend to favor large corporations which have more sophisticated and costly marketing strategies than smaller businesses.

Thank you for your consideration of our comments and recommendations.

Sincerely,

Catherine Porter

Catherine Porter, JD

Policy Director

California Healthy Nail Salon Collaborative

catherineAporter@gmail.com

(510) 985-1146



*Advancing public policy to
improve the health and safety
of workers and the community.*

CIHC Board:

President, Chris Loucz-Davis, MS, CIH
The Environmental Quality Organization, LLC
Lafayette, CA
(925) 335-1774

Vice President, Ann Hutton, CIH
Pacific Health & Safety, Inc.
Mission Viejo, CA
(949) 331-2732

Treasurer, Richard Bohrer, MS, CIH
Adaptix, Inc.
Sacramento, CA
(916) 705-2604

Secretary, Edward Krasenberg, Ph.D., CIH
Mullins-Grossman Information Systems
Cyber & SIGINT Systems
Arcadia, CA
(916) 570-4032

Directors:

Patricia Bartz, MS, CIH
Harris & Leo Environmental Sciences, LLC
San Francisco, CA
(415) 387-0236

Gloria Chan, CIH
County of San Diego Environmental
Health/DEHP
San Diego, CA
(619) 594-2240

Mido J. Awamleh, PhD, CIH
UCLA School of Public Health
Los Angeles, CA
(310) 994-7087

Samantha Chua, CIH
General Atomics
San Diego, CA
(619) 455-3814

Howard Spidman, PE, CIH, CSP, NEHS
Health Science Associates
Los Alamitos, CA
(714) 220-3622

Alternates:
Joni Cohen, MPH, CIH
The Cohen Group
San Jose, CA
(858) 340-9737

Ann Guzman, CIH
U.S. Navy
San Diego, CA
(619) 377-6525

Jayne Steinman-Lyde, CIH
Health Science Associates
Los Alamitos, CA
(714) 220-3922

Patricia Muzell, CIH
KISA Safety & HAZMAT Consultants, Inc.
El Dorado, CA
(530) 622-7155

Leo Mariani, MPH, CIH
Newport Beach, CA
(949) 772-1133

Special Advisors:
Larry Gibbs, MS, CIH
Stanford University
Palo Alto, CA
(650) 723-7603

**Sacramento Advocacy
Coalition Barunkin
CIHC Legislative Office
Sacramento, CA
(916) 647-7141**

October 10, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

The California Industrial Hygiene Council (CIHC) respectfully submits the following comments regarding the draft regulations for Safer Consumer Product Alternatives, Chapter 55 of Division 4.5 of Title 22, California Code of Regulations.

Founded in 1990, the CIHC represents the occupational and environmental health profession in California and is affiliated with the American Industrial Hygiene Association (AIHA), an 11,000 member national organization, as well as the International Occupational Hygiene Association (IOHA), which represents the global community of Occupational Hygiene organizations in over 27 countries.

Our comments include those of our California membership, as well as comments from members of the national AIHA's Stewardship and Sustainability, as well as Risk Assessment Committee science experts.

GENERAL COMMENTS:

1. In general, while this proposed Regulation reflects abundant efforts by the Department to engage and align the great number of California stakeholders impacted by the final Regulation, DTSC may well want to consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the probability of harm. A more focused approach could well address the practical problems raised by the scope and complexity of this draft. All three components—hazard, exposure and probability of harm— must be considered in characterizing “exposure to chemicals” and a consistent, defined approach should be described in the regulations.
2. Undoubtedly, the Regulation’s provisions will require significant data collection, analysis, and reporting. The required projections of resource consumption requiring significant data collection, analysis and reporting include, among others—water consumption and conservation; production, in-use, and transportation energy inputs; energy consumption

and efficiency; reusability and recyclability; and a critical hybrid scientific and operational experience knowledge capacity. Has all this been factored in? To the extent possible, the proposed Regulation should avoid reaching an end product that is heavily bureaucratic and/or unreasonably controlling and rigid. It goes without saying that it needs to be “user friendly” in order to achieve its goals.

3. A number of the Regulation’s provisions have applicability under California’s Health & Safety Codes. Although the Regulations cite “consumer products” as its primary focus, the operational workplace implications in the workplace are potentially quite significant and need to be assessed by the regulatory arm that holds workplace jurisdiction in California. It is important that Cal-OSHA weigh in on this proposed draft Regulation in terms of its ability to not only effectively carry out its mandate under the provisions as presently cited, but to define areas of overlap and intersection requiring a seamless approach with Cal-EPA.
4. Given California’s economy and impact in the global market, we would suggest that this proposed regulation could benefit from an independent peer review by a broader based global science organization (National Academy of Sciences, NAS, is one such body).

SPECIFIC COMMENTS:

1. **Reliable Data, Exposures and Toxicology Studies:** With regard to exposure, 69502.2(b) (2) states that DTSC shall consider exposures to chemicals, considering reliable information regarding exposures to the chemical and reliable information demonstrating the occurrence of exposures to the chemical. It is not clear how this will be considered. The potential variability in data sources, reliability and reproducibility is significant potentially and impacts final assessment determinations. Protocols must be defined for determining representative exposures to chemicals.

Furthermore, we suggest that DTSC consider being consistent with other agencies, including ECHA for instance and its regulations under REACH, to judge the studies used. For instance, the Klimisch Score is a method of assessing the reliability of toxicological studies, mainly for regulatory purposes, and is widely used both here and abroad. It is the standard method used in the European Community regulatory scheme. It assigns studies to one of four categories—reliable without restriction; reliable with restriction; not reliable; and not assignable.

2. **Hazard and Exposure Assessment Tools and Methods (for Alternative Assessments):** This Table, used as the base set of elements for DTSC’s October 9, 2012 Alternative Analysis Workshop, is fairly comprehensive. Missing, however, is mention of a tool for scoring the reliability of toxicology studies. All studies are not equal, nor are they reliable. Also missing are tools to consider the “occupational” segment of hazard and exposure assessments employed to determine appropriate alternative analyses; what are listed are predominantly environmental tools. At this time, the “occupational” segment is supposed to be part of the “public health” discussion within the framework of this proposed Regulation. The federal agency resources whose primary responsibility governs “occupational” segments, the

National Institute of Occupational Safety & Health (NIOSH) and the federal Occupational Safety & Health Administration (OSHA) should be leveraged.

3. **Accreditation Bodies and Certified Assessors:** These sections presently describe a very cumbersome process and should be reserved for those with less than ten (10) years of experience in the industry. One option is to substitute this section with “accredited, certified or registered in appropriate disciplines by nationally recognized professional regulatory bodies, some of whom include the American Board of Industrial Hygiene (ABIH), the American Industrial Hygiene Association (AIHA), the American Board of Toxicology (BOT), and members of the American Chemical Society (ACS) Green Chemistry Roundtable. ”

As a case in point, individuals applying to take the Certified Industrial Hygienist (CIH) exam must meet the education qualifications spelled out by the American Board of Industrial Hygiene. A typical qualified candidate has a Bachelor’s Degree in biology, chemistry, chemical engineering, sanitary engineering, physics, industrial hygiene, environmental health, safety or toxicology. Many qualified candidates have graduate degrees as well. In addition, the candidate must have academic or continuing education course work specifically addressing industrial hygiene, environmental impacts, toxicology, community health impacts, hazard and risk anticipation, recognition, evaluation and controls, as well as a number of years of work experience. These criteria help ensure that practitioners have the basic academic and work experience underpinnings to take on selected tasks. Similar rigor in skill and experience exists with others accredited by national professional regulatory bodies.

Section 69508 (a) presently references the qualifications and certification for Certified Assessors, basically a Bachelor’s Degree in science or engineering and two years of experience. This grossly underestimates the training, skill and experience required to be a Certified Assessor who is able to render thoughtful determinations in product development and alternatives. The financial stakes are very high. It goes without saying that there need to be more than two years of experience required or an exemption of certification for those with substantial product related experience (i.e. ten years).

4. **Life Cycle Assessments (LCA):** The Hazard Assessment Tools and Methods table referenced earlier is very comprehensive and is being contemplated for conducting Alternatives Assessments (AA). In reviewing the proposed regulations, there is clearly an underestimation as to what it actually takes to conduct a Life Cycle Analysis (LCA), to address the uncertainty, validate comparative analysis results, and to have the level of expertise required to do this work. Overall, while the Table provides a list of references, it fails to understand the practical side as to what it takes to do this work. Certainly the timeframes and resources for conducting an AA reflect a naiveté and will be very challenging for manufacturers to meet. Additional specifics with regard to the AA and LCA follow:

- **AA Timeframe-** The regulation states that a preliminary AA report must be submitted within 180 days after product becomes a “priority product” and the final AA assessment must be completed within 12 months. This timeframe seems very unreasonable given how resource intensive it is to: 1) consolidate the inventory across the supply chain

(inputs into the LCA), 2) conduct the impact assessment, and 3) analyze and validate the results.

- **Accuracy and Uncertainty-** LCA results are subject to a high amount of uncertainty, especially if there is a lack of primary datasets and one needs to rely on secondary datasets available in databases through resources such as SimaPro. This can result in higher levels of uncertainty, making the data difficult to interpret. This is a common problem faced by LCA professionals. It is hard to imagine that one can ask a manufacturer to make a change to their product based on such uncertainty. **Missing** is an evaluation of the quality, reliability and end use of these LCA tools; this is not presently reflected. A compiled list absent reliability, quality and end use features has relatively modest value.
- **Shifting Burdens-** When comparing products through LCA, it is often the case where one may see an environmental benefit in one category, but which in parallel has a negative impact in another. It is critical that the intended use of the product be factored in when evaluating the results as one may simply shift the environmental burden by choosing one product over the other... resulting in an unintended consequence.
- **ISO Standards-** When conducting a comparative LCA, the ISO standards call for a validation process. This is an element that is both costly and adds time. Is the intent of the regulation to adhere to ISO standards for LCA? If so, the validation process and extra time element needs to be factored in.
- **Resource Intensive-** These types of studies are very resource intensive and extremely costly. How is this aspect addressed in the Regulation?
- **Expertise-** The regulation indicates that the AA process must be completed by an Assessor who is certified by an accredited body designated by the DTSC. There are no specifics at this time in the regulation; this is much too open ended.

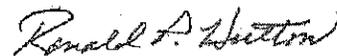
The California Industrial Hygiene Council (CIHC), comprised of members dedicated to the anticipation, identification, evaluation and control of occupational and environmental health risks, is available to assist in the scientifically sound development of this Initiative's goals. At the end of the day, our charters remain the same—to protect our workers and the public!

We appreciate your consideration of our concerns.

Sincerely,



Chris Laszcz-Davis, MS, CIH, AIHA Fellow
President, CIHC
P: (925)-330-1774
ChrisLD@EQ-Organization.com



Ron Hutton, CIH, AIHA Fellow
Vice-President, CIHC
P: (949)-331-2732
rehutton777@aim.com

CC:

The Honorable Matt Rodriguez, Secretary, CalEPA

Miriam Ingenito, Deputy Secretary, CalEPA

Kristin Stauffacher, Assistant Secretary, CalEPA

Nancy McFadden, Cabinet Secretary, Office of the Governor

Mike Rossi, Senior Business & Economic Advisor, Office of the Governor

Cliff Rechtschaffen, Senior Advisor, Office of the Governor

Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

Debbie Raphaeli, Director, Cal-EPA DTSC

Ellen Widess, Chief, Cal-OSHA



October 11, 2012

Ms. Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Via Mail and Email: gcregs@dtsc.ca.gov

Dear Ms. Von Burg:

On behalf of the California Manufacturers & Technology Association, we appreciate this opportunity to comment on DTSC's proposed Safer Consumer Products Regulations. California Manufacturers & Technology Association (CMTA) is a trade association with the mission to improve and preserve a strong business climate for California's 25,000 small and large manufacturers, processors and technology-based companies. California manufacturers employ 1.5 million Californians and contribute billions of dollars to the state's economy. CMTA membership includes over 750 businesses representing chemical, aerospace, high-tech, biotech, pulp and paper, glass, oil, steel and others. CMTA lobbies the state legislature and regulatory agencies to promote policies on issues such as the one before us today to assure the continued viability of California's manufacturing community.

As a Green Chemistry Alliance (GCA) member, we appreciate the effort DTSC has once again invested in its latest effort, but believe it has again missed the mark. We again encourage DTSC to focus on regulatory alternatives, such as those submitted to DTSC by GCA on November 1, 2010, which have a greater chance of being implemented, passing legal review and achieving the stated objectives of the Regulation. See Attachment 3. We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This approach will enable the Department to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme that is far in excess of that which it needs to conduct the initial phase and far in excess of its own resources to support. The fact that John Warner, who is widely viewed as the Father of Green Chemistry, disagrees with the approach taken by DTSC should cause second thoughts.

While we definitely support the intent of AB 1879 and SB 509, we do not believe that these regulations, as drafted, will remove politics from decision making and establish a scientific process to determine how products are selected, alternatives are assessed, and how response actions will be meted out. Businesses desires certainty and these nebulous regulations guarantee uncertainty. A company has no idea if or when its products will be selected to be reviewed. There is no criteria spelled out on how priorities will be set. It appears that DTSC has reserved

the right to change the rules as they go along. As was evidenced in yesterday's Alternatives Assessment Workshop, DTSC has yet to decide what format, methodology or tools they will accept. The estimated cost for companies to comply appears to start at a million dollars. While this is a huge disincentive for large companies to do business in California, there is little chance that small or medium size manufacturers can absorb that type of cost. They will be simply out of business. The same fate will befall many small and medium size retailers or distributors if they bring products and chemicals into the California from outside the state or outside the country. There is no anti-trust clause in the proposed regulations which would protect companies wishing to band together to share in the cost from lawsuits for collusion.

In Attachment 1, CMTA has included detailed comments discussing four fundamental flaws: 1) Lack of Clarity, 2) Conflict with Existing Authorities and Laws, 3) Exceeding Authority Granted by Underlying Statue and 4) Preemption, and Inappropriate Intrusion into the Business Decision Making Process, Loss of Proprietary Information and Competitive Disadvantage. Attachments 3-6 are referenced in Attachment 1. Specific citation and examples are included to help DTSC understand why the Proposed Regulation has not met the requirements of the Administrative Procedures Act nor of CEQA.

Attachment 2 comments on DTSC's Economic and Fiscal Impact Statement and Economic Analysis. DTSC obviously brushed aside its responsibility to evaluate the economic impact of these regulations. Virtually every question on your form was answered unknown. It is our opinion that the Andrew Chang and Company estimated negative impact of potentially as high as \$150 million dollars (See the attachment to comments from the California Chamber of Commerce) to the California economy over the next 25 years is conservative if anything. The real costs incurred by the companies, the state and ultimately the consumers are front end loaded while the nebulous benefits will only be realized far in the future.

The lack of an established meaningful *de minimus* is also of extreme concern. Manufacturers will need to hire experts and toxicologists to justify the threshold below which the chemical of concern poses a risk in their product both in use and in the environment. We have been told by firms that must do much the same thing in front of the Food and Drug Administration that this generally costs them somewhere between one and 6 million dollars. This number may be low. The FDA only looks at the effects of the product on public health not on the environment as a whole.

DTSC's draft regulations propose to use a list-of-lists approach to select Chemicals of Concern. DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as Chemicals of Concern. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.

CMTA supports a two step approach, 1) “chemicals under consideration” and 2) “chemicals of concern.” In this regard, we concur with GCA’s recommendation that DTSC begin by identifying their list of 1200+ chemicals of “Chemicals Under Consideration.” DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bio-accumulative and toxic (PBT) in the environment as designated by US EPA and others. A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.

We are concerned that the purpose of the current list will be misconstrued by companies in the supply chain as well as by governments, NGOs, and in particular by members of the general public whose understanding of technical issues may be severely limited, leading to unfounded fear. It is very likely that the chemicals identified by this process will have a stigma attached to them that will cause their use to be unnecessarily challenged or questioned, even though the chemicals may have already undergone an assessment or be safe in specific applications.

The definition of “functionally acceptable” is inadequate. Durability, safety, performance consistent with brand name marketing, aesthetics and consumer acceptability are all factors that companies have to take into consideration when formulating a product.

The fact that naturally occurring constituents and non-intentionally added substances fall under this regulation is troubling. There are substances like lead that are virtually ubiquitous. Our manufacturers are using (and are being pressured to use) more and more recycled materials in their processes. Since you have not set a *de minimus*, there is always the possibility that a substance on your chemical of concern list could be detected as testing capabilities become ever more refined. These companies do not want to have the safety of their product questioned and have no desire to fall under your costly program.

The timeframes detailed in the regulation do not provide the necessary flexibility for specialized applications. For example, the requirements in Federal contracts cannot be easily or quickly modified. California manufacturers could be significantly disadvantaged or find themselves excluded from such contracts. Complex goods require years of design, supply chain complexity, research and development, testing and validation. This regulation does not appear to take these actions into consideration.

The broad base approach of this proposed regulation seems to be built on the premise that the bulk of products manufactured are unsafe, the companies that produce them do not care and that the Department is going to have to force them to eliminate the toxic materials in their products. This couldn’t be further from the truth. That doesn’t mean that there aren’t companies that do not care or are not cognizant of the dangers that their products present, but they are few and far between. This regulation places the onus on the back of the manufacturing community as a whole rather than the “bad actors.” You cannot regulate innovation. That takes time, resources and a will. Few companies have the resources to innovate. This regulation does not encourage innovation. It will stifle it.

CMTA does not believe the currently proposed regulation is workable, practical and legally defensible. It will hurt the California economy and add significant cost to the products that California residents buy. DTSC will be susceptible to political pressure. It cannot fall back on regulations that call for specific action based on scientific principles because they have not established any standards.

We thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael J. Rogge". The signature is written in a cursive, somewhat stylized font.

Michael J Rogge
Policy Director, Environmental Quality

cc. The Honorable Matt Rodriquez, Secretary CalEPA
Miriam Ingenito, Deputy Secretary, Cal EPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Officer of the Governor
Cliff Rechtschaffen, Senior Advisor Office of the Governor

Attachment 1
October 8, 2012

CMTA Concerns with DTSC's Proposed Regulations, R-2011-02

Safer Consumer Products

I. Lack of Clarity

The DTSC purports to provide clear compliance direction yet almost every page of the regulation contains wording that provides DTSC with unprecedented discretion in the decision making process and creates confusion and uncertainty for the regulated community. Phrasing such as "the Department may", "to the satisfaction of the Department", "the Department may at any time" add unnecessary confusion to an already complex regulation. The removal of this vague and subjective language almost always improves the clarity of the regulation and does nothing to diminish the requirements stated in the regulation. Additional examples of the lack of clarity include:

- a. Additions to the Chemicals of Concern List: Section 69502.2(b)(1)(A) has been amended to include the word "ability" in place of "potential" in the October 2011 version. If this is intended to direct DTSC to look at the physiochemical properties of a chemical to make the determination of hazard rather than simply grouping chemicals into categories that might be acceptable. However, if the intent of DTSC is to make certain that in the application (how it is used in the consumer product) it is possible for the chemical to have the hazard trait effect, then it must be clarified.
- b. There are several areas where DTSC has not provided sufficient clarity for the regulated community to comply with the regulations. Examples include the following questions:
 - i. It is unclear how DTSC intends to identify a list of 1200 chemicals of concern ("CoC"). DTSC states that over 4500 chemicals are on the twenty-two lists and that 500 drugs and pesticides were removed. DTSC has not provided any information on the filtering steps to reduce this to 1200. In addition, we understand that DTSC has further filtered the CoC list to ~185 chemicals in the Workplan but again has not provided any transparency regarding the steps for filtering or criteria. There is no indication in the Regulation about how and when the 185 chemicals in the CoC Work plan will be developed or communicated.
 - ii. Dropping the language about "Priority Product/CoC combination" has created an uncertainty as to whether this signals an intention by DTSC to require alternative assessments that are not connected to a priority

product and CoC determination. If that is the case, this would increase the unworkability of the overall regulation.

- iii. In §69503.2 (b), DTSC refers to “Key Prioritization Factors”. Those factors are listed as follows.

- (1) The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts; and

- (2) There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

The term “significant ability” is used in both of these critically important prioritization factors yet the term is not defined within the regulation. The term as written is vague, arbitrary and inappropriate as a regulatory standard. It does not provide the regulated community with any reference or benchmark that can be used in the evaluation of alternatives or assessing the suitability of chemicals for use in products. Without clarity around such critical and fundamental concepts, compliance with the remainder of the regulation becomes difficult if not impossible for the regulated community.

- iv. The reference on page 29, line 5 (g) referencing Initial Priority Products List, focused on chemical meeting adverse impacts/exposures and available information prior to 1/1/2016 is unclear. In the “Changes” document it is described as limiting chemical selection to 7 hazard traits and from the 22 lists, but that is not clear in (g). DTSC must clearly identify how products will be prioritized and what criteria will be used.
- v. The necessity for the final report to contain analyses on ingredients in the priority product beyond the named CoCs is unclear and goes beyond the scope of DTSC’s authority granted by the underlying statute. The final report should be focused on the priority product and CoC combination and alternatives that were selected.
- vi. DTSC has assumed that a product will be ‘static’ during AA period. This exemplifies DTSC’s lack of understanding of supply disruptions, ongoing marketing plans, etc. It is also unclear whether DTSC has considered whether a CoC could be eliminated during the AA period, where

concentrations are changed and/or substitutes are put in with AA Paperwork submitted following the elimination or change.

- vii. DTSC has not clearly identified the role of the Certified Assessor. DTSC should clarify whether the Certified Assessor is one who manages the work or one who does the work.
- c. Section 69503.5. AA Threshold Exemption. The ease or difficulty of removing a chemical of concern from the product is a very subjective measure and a poor criterion to judge the potential risk of an adverse public health or environmental impact. This highlights the need for exposure to be the primary criteria. If the product does not expose a consumer to the hazard, then it is unreasonable and unnecessary to devote the time and/or additional resources to determining thresholds for the chemicals. Generally, this section continues to lack clarity and certainty for the regulated community to understand what will be required and how to comply.
- d. Section 69506.2. AA Report Supplemental Information Requirements. This section provides that the Department may, at any time, require a responsible entity to provide information supplementary to the final AA report for the Department to select and ensure implementation of one or more regulatory responses or to fill one or more of the information gaps identified in the final AA report if the Department determines the information is needed to evaluate the initial regulatory response. It is significant to note that this section contains no standards as to when the Department will or will not choose to require supplemental information to be provided. It is not clear what kind of supplementation information might be required. Without guidance on what kind of information could be requested, this could represent significant time and money being allocated to developing potentially unnecessary data. The lack of clarity around this lends itself to controlling the market, especially in cases where DTSC is continually asking for additional information without justification. This could lead to companies deciding to exit the market or given the costs, cause significant financial expenditures resulting in loss of economic viability of the alternative or the ongoing viability of the business. The Department has afforded itself complete unfettered and arbitrary discretion.
- e. Section 69506.3. No Regulatory Response Required. This section provides that no regulatory response is required if the Department determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts. Perhaps the Department believes that referring to preventing or limiting public health and environmental impacts is an adequate standard, but the truth of the matter is that it is little more than a tautology.

That is, no regulatory response is required if the Department determines that no regulatory response is required. The standards in this section should be clearly identified.

- f. Section 69506.5. Use Restrictions on Chemicals of Concern in Consumer Products. As noted with respect to section 69506.4, this section does not include the provision, “except as provided in section 69506.3.” This section imposes restrictions on the use of one or more chemicals of concern and a selected alternative or in a priority product for which no alternative is selected or on the use of the product itself. The section spells out what the use restrictions may be, but it contains no standards as to when these restrictions may be imposed. The section simply says, “The Department may impose restrictions.” Again, the Department has conferred unfettered and potentially arbitrary discretion on itself.
- g. Section 69506.6. Product Sales Prohibition. Subdivision (a) of this section provides that the section does not apply to a product that does not contain any chemical of concern above the applicable alternatives analysis threshold. Subdivision (b) provides “except as provided in section 69506.3 ” a sale prohibition may be imposed if a selected alternative contains one or more chemicals of concern or if no alternative is selected for a priority product and “there is a safer alternative that does not contain a chemical of concern and that is both functionally acceptable and technically and economically feasible.” Perhaps a sales prohibition is appropriate in the circumstances set out in subdivision (b). However, note that subdivision (d) provides that the Department may issue a notification prohibiting the sale of a product “notwithstanding that there are no current identified safer alternatives that are both functionally acceptable and technically and economically feasible.” Subdivision (d) contains no standards as to when the Department would issue a notification prohibiting the sale. It should be noted that subdivision (d) supersedes subdivision (b) by allowing the Department to prohibit the sale whenever it chooses. Again, the absence of any standard enables the Department to impose unfettered and potentially arbitrary discretion.
- h. Section 69506.9. Advancement of Green Chemistry and Green Engineering. This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals. No standards are set out as to under what conditions the Department would invoke that authority. It is also unclear whether the Department will consider financial impacts to the company of such research and development projects, who will own the intellectual property developed as part

of the project and if any considerations will be made for out of state or out of country existing projects. The lack of clarity around the criteria for initiating a research and development program could lead to a variety of outcomes that would be harmful to companies doing business in California. As an example, on page 26 of the supporting Economic Analysis prepared by Matthew Kahn, he indicates "The funds raised from such firms can be used to help smaller firms finance innovation." As written, the proposed regulation leaves open the possibility that larger firms could be forced to fund R&D programs for the benefit of smaller competitors. A program of this type is highly inappropriate, anti-competitive and provides DTSC with unfettered and potentially arbitrary discretion to select winners and losers in the marketplace.

- i. Section 69506.10. Regulatory Response Selection and Reevaluation. Subdivision (a) of this section provides that the Department may impose one or more regulatory responses specified in the preceding sections to situations other than those specified in those sections. The Department goes on to say that the Department may periodically reevaluate any regulatory response to determine if changes are needed based upon changed circumstances or information. As noted before, many of those sections do not contain specified situations. But here, the Department has conferred complete discretion on itself to impose any regulatory response under any set of circumstances that it may choose. Those situations must be clearly identified.
- j. Section 69506.4. Product Information for Consumers. This section applies to "selected alternative products, Priority Products for which an alternative is not selected, and Priority Products which remain in commerce in California pending development and distribution of an alternative product for longer than twelve (12) months." In other words, it applies to all products going through the AA process. It should be noted that this section does not contain the same provision as sections 69506.6, 69506.8, stating "except as provided in section 69506.3" the requirements apply. The absence of that provision in this section as well as sections 69506.5 and 69506.7 might not in and of itself pose a serious problem because section 69506.3 states that no regulatory response under section 69506.4 through 69506.10 is required if the Department determines that no regulatory response is necessary. However, the presence of the "except" provision in sections 69506.6 and 69506.8 creates an ambiguity as to why that provision is not also included in sections 69506.4, 69506.5, and 69506.7. DTSC must clarify the intent of these sections and eliminate the ambiguity.
- k. Section 69506.5. Use Restrictions on Chemicals of Concern in Consumer Products. As noted with respect to section 69506.4, this section does not

include the provision, “except as provided in section 69506.3.” The same point made with respect to section 69506.4 applies here.

- I. Section 69506.7. Engineered Safety Measures or Administrative Controls. This section, like section 69506.4 and 69506.5 do not contain the provision “except as provided in section 69506.3.” Again, an ambiguity is created by its absence. This section allows the Department to impose requirements that control access to or limit exposure to chemicals of concerns, to reduce the likelihood of adverse public health and/or environmental impacts. Subdivision (b) of this section sets out three circumstances when engineering or administrative controls may be imposed by the Department. The question is whether those standards make sense in the context of the regulatory response.

II. Conflict with Existing Authorities and Laws

- a. Occupational Health and Safety Act (OSHA)– The Proposed Regulations provide no additional benefit to workers in California and the inclusion of the category of “workers” should be eliminated. The provisions of the Proposed Regulations include workers as sensitive subpopulations and chemicals that might be used in the workplace. The DTSC is preempted by existing OSHA standards from doing this. 29 C.F.R. §1910. The OSHA regulations are applicable to “employments performed in a workplace in a State...”. 29 C.F.R. §1910.5(a). The regulations specifically state that “[i]f a particular standard is specifically applicable to a condition, practice, means, method, operation, or process, it shall prevail over any different general standard which might otherwise be applicable to the same condition, practice, means, method, operation, or process. 29 C.F.R. §1910.5(c)(1). The addition of “workers” as a potentially sensitive subpopulation also appears to duplicate the existing authority of Cal/OSHA to protect workers from unreasonable exposures to chemicals. California State Plan, Section 19 OSHA (1970), approved May 1, 1973, and certified August 19, 1977. Per the agreement between the State of California and OSHA, the state plan “applies to all public and private sector places of employment in the state, with the exception of Federal employees, the United States Postal Service, private sector employers of Native American lands, maritime activities on the navigable waterways of the US, private contractors working on land designated as exclusive Federal jurisdiction, and employers that require Federal security clearances.” See also, 29 CFR 1952.172. The potential for DTSC’s Proposed Regulations to conflict with the existing authority or rules established for workplaces makes this addition an invalid exercise of DTSC’s authority.

- b. End of Life Management Requirements. As written, the Proposed Regulations potentially conflicts with existing End of Life Management programs.
 - i. In subdivision (c), the Department apparently seeks to exempt existing EPR programs. However, it does not state it specifically. Rather, it authorizes the responsible entity to substitute an alternative end of life management program that achieves “to the maximum extent feasible, the same results as the program required by this section.” It provides that a responsible entity may not substitute an alternative end of life management program unless it receives advanced written approval from the Department. Hence, the newly established paint program could be encumbered with duplicate end of life management programs administered by DTSC as well as by CalRecycle. In addition, by requiring DTSC approval of end of life management programs, this would be in conflict with the underlying statutory authority that prohibits DTSC from duplicating or adopting conflicting regulations for product categories already regulated or subject to pending regulation. H&S Code Section 25257.1(c).
 - ii. The end result of the Proposed Regulations will potentially be in conflict with Public Resources Code §41780.02, requiring municipalities to develop strategies for achieving the state goal of 75 % recycling rate. Putting the programs in the hands of manufacturers may provide problems for municipalities who are currently developing strategies for recycling that do not rely on manufacturers to recycle certain products under the guise of the Proposed Regulations.
 - iii. Manufacturers that utilize recycled materials to produce their products may move to virgin materials to mitigate business risk. Manufacturers cannot control the quality or composition of recycled material streams and therefore cannot fully attest or certify to the presence or absence of Chemicals of Concern in their products. Given the potentially low CoC threshold limits and the liability associated with marketing a product containing a CoC, a manufacturer may move to virgin materials to mitigate that business risk. With fewer manufacturers using recycled materials, landfill waste generation would increase. Existing end of life management programs, such as CalRecycle’s 75% recycling goal, would be difficult or impossible to achieve as demand for recycled materials declines.

III. Exceeding Authority Granted by Underlying Statute and Preemption

- a. Regulatory Response Green Chemistry and Green Engineering Advancement, Regulation Section 69506.9 – The requirement goes beyond the DTSC’s statutory authority by not limiting when DTSC “may require” the R&D project to those circumstances when “no feasible safer alternative exists”. The statute provides that DTSC “may impose a requirement to fund green chemistry challenge grants where no feasible safer alternative exists.” H&S Code 25253(a)(8). DTSC must limit the discretion to impose the regulatory response to fund the grant to only those situations where an alternative does not exist.

- b. Reporting – DTSC has frustrated the authority that it was provided to “devise simplified and accessible tools that ... consumers can use to make consumer product ... purchase decisions.” H&S Code 25253(c). Nothing about the proposed regulation is simplified or accessible. So much information is contemplated to be placed on DTSC’s website that it will be impossible for the reasonable consumer to sift through the information and make a purchasing decision. DTSC seems to be counting on consumers to do extensive research for every purchase of a consumer product, not something most consumers have the time, patience, or desire to do. It seems that it is likely that only an infinitesimal number of California consumers might take advantage of the access to such complex information. The information available on the website should be clear, focused and easy to understand. The complicated AA reports, the notices of noncompliance, and notices of requests for alternative assessment thresholds, as the final regulatory response determination (cite to all) fail to provide a simplified and accessible tool for consumers. DTSC’s proposal also does not create a simplified and accessible tool for consumer product manufacturers, distributors and retailers. H&S Code 25253(c). DTSC has drafted the regulations to allow for possible unfettered and arbitrary discretion to be held by the Department and therefore fails to be accessible on the face of the regulation.

- c. Section 69506.11. Exemption from Regulatory Response Requirements. This section is ostensibly designed to implement the provision in section 25257.1 of the statute. Subdivision (b) of the statutory section provides that, “This article does not authorize the Department to supersede the regulatory authority of any other department or agency.” Subdivision (c) provides that, “The Department

shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.” Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response “substantially duplicates” one or more requirements of another California or federal regulatory program, “without conferring additional public health or environmental protection benefits.” Three points need to be made with respect to this section:

- i. First, nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department, providing the article does not authorize the Department to supersede, duplicate, or adopt conflicting regulations. The Legislature has imposed responsibility on the Department to implement that provision. It does not contemplate imposing the burden on responsible entities.
- ii. Second, with respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. Again, this exceeds the Department’s authority. Nothing in this section with respect to duplication contemplates that DTSC or the Department may duplicate other regulatory programs if the Department is conferring greater public health or environmental protection.
- iii. The third point to be made with respect to this section is that once again the Department has ignored the fact that subdivision (b) of section 25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, supersedes the other agency’s regulatory program. The Department is specifically prohibited by section 25257.1 from doing this, yet, nothing in the regulation acknowledges that.
- d. CPSA - Generally the federal government has indicated that it intends to occupy the field with the Consumer Products Safety Act (CPSA). 15 U.S.C. § 2051 *et seq.* In passing the Consumer Product Safety Act, the Congressional findings point out that “control by State and local governments of unreasonable risks of injury

associated with consumer products is inadequate and may be burdensome to manufacturers.” 15 U.S.C. §2051(a)(4). CMTA encourages DTSC to review the comments submitted by the Grocery Manufacturers Association, Toy Industry Association, Consumer Specialty Products Association, and others to understand how the CPSA preempts certain provisions of the Proposed Regulations and amend the requirements in order to avoid the inappropriate duplication of this law and regulation.

- e. Toxic Substances Control Act (“TSCA”) – Under TSCA Section 18, states are preempted from enacting requirements for a chemical substance or mixture that is regulated under Sections 5 or 6 unless the state requirement is identical to the federal requirement, implements another federal law, or prohibits use of the substance or mixture within the state. A state may ask EPA for authorization to exert a significantly higher degree of protection from risk than does the federal standard, provided that protection is not inconsistent with federal law. DTSC has not indicated that it has asked EPA for the authority to exert a significantly higher degree of protection from risk than does TSCA. DTSC also has not provided EPA with an indication that the Proposed Regulations will not result in inconsistencies with federal law. If DTSC has done so, this should be a part of the public record.

- f. Food and Drug Administration (“FDA”) – On December 3, 2010, Keller and Heckman, LLP submitted comments to DTSC on behalf of the Food Packaging Coalition, referencing an earlier submission on November 1, 2010 by that same coalition of trade associations. See attached December 3, 2010 letter. These documents provide a full analysis of the regulatory duplication that is created by the Proposed Regulations and the authorities granted to the FDA. DTSC must recognize the duplication that would be created by the Proposed Regulations and provide an explanation for how DTSC plans to deal with this issue, as well as duplication in general. It has been suggested that companies that identify duplication issues should bring those to the attention of DTSC during the priority product review process, but this does not seem adequate. DTSC should develop a clear process for bringing up regulatory duplication issues and how they will be addressed.

IV. Inappropriate Intrusion into the Business Decision Making Process, Loss of Proprietary Information, and Competitive Disadvantage

The regulation as proposed continues to be intrusive, onerous and potentially destructive to companies doing business in California and the general California economy. The stated purpose of the regulation is to provide “safer” products to consumers. However the regulation as currently proposed seems to be more intent on providing the DTSC and the public complete and total access to the business decisions concerning product management of all private industry doing business in California. The continual requests for information such as product formulations, product selection decisions, supply chain information, sales volumes, profit margins, rationale for decisions and other business critical information is unnecessary, harmful to business and innovation while doing nothing to advance the stated purpose of the regulation. This approach also disadvantages small businesses. A small business that has devoted the majority of its resources to developing its current product offerings may not be able to afford both the technical requirements and the extensive administrative and bureaucratic burdens of the AA process.

- a. Throughout the Proposed Regulations, DTSC assumes that Responsible Entities will be required to provide sensitive information and unless the company can meet certain requirements, that information will be made available to the public on easily accessible websites. Such information includes market information (Section 69505.4(a)(1)(C)), decision making (Section 69505.4(b)), supply chain information (Section 69505.5(d)), targeted customer base (Section 69505.1(g)(2)(E)), and chemical formulations and ingredients (Section 69505.5(j)(2)(C)). Such information can be used by competitors to copy the work that has been done, reverse engineer the solutions identified, or in the case of market information be used in an anti-competitive manner. See attached Comments from FTC to EPA, Docket No. EPA-HQ-OAR-2009-0924 related to EPA’s Proposed Confidentiality Determinations for Data Required Under the Mandatory Greenhouse Gas Reporting Rule and Proposed Amendments to Special Rules Governing Certain Information Obtained Under the Clean Air Act.
- b. In Article 10, DTSC has failed to appropriately protect trade secrets and other proprietary information considered by companies to be confidential business information (CBI).
 - i. Subdivision (a) requires a Responsible Entity making a claim for trade secret protection to provide specific information. Three requirements are of particular concern because providing such substantiation is in itself requiring the disclosure of sensitive information:
 1. Paragraph (6), the estimated value of the information to the person and the person’s competitors;

2. Paragraph (7) the estimated amount of effort and/or money expended by the person in developing the information; and
 3. Paragraph (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering.
- ii. In addition, paragraph (10) requires, a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed. In the event that DTSC rejects a Responsible Entity's claim of CBI, this substantiation information disclosed by DTSC could be used by a competitor to damage the Responsible Entity's business in an unfair and potentially anti-competitive manner.
 - iii. Further, paragraph (11) requires the signature of the person's general counsel or other executive, certifying under penalty of perjury that there is a basis for asserting a trade secret protection. This is an inappropriate requirement as a general counsel is unlikely to have the substantive knowledge to know whether there is a basis for claiming trade secret protection for chemical specific or marketing information. The company should be able to identify the person with best knowledge to certify such a claim.
 - iv. Subdivision (c) requires in paragraph (2) a redacted copy of the documentation being submitted which shall exclude the information for which trade secret protection is claimed. The Department may make the redacted copy of the documentation available to the public at its discretion. The last provision, making the redacted copy available at the discretion of the Department is inconsistent with the provision in Section 69501.5 (b) (6) where it says it "shall" put on its website "a full or redacted copy of each document."
 - v. Subdivision (e) provides that if the documentation supporting the claim of trade secret contains information that is itself trade secret, the supporting documentation shall be supplied in both the complete and redacted form.
 - vi. Subdivision (f) ostensibly is included to implement the provision of the statute providing that the section on trade secret protection "does not apply to hazardous trait submissions for chemicals and chemical

ingredients pursuant to this article." Subdivision (f) specifically says that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission. The latter portion of the regulation arguably exceeds the scope of the statutory authority precluding protection for hazard trait submission but not chemical identity.

- vii. Subdivision (g) provides that trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the claim is for a proposed alternative to a chemical of concern in a priority product subject to certain requirements. Those requirements include demonstrating to the Department's satisfaction the chemical is a new chemical or a new use of an existing chemical, provide the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing chemical of concern of the priority product, and comply with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret.

V. Legally Indefensible

Under Government Code §11350(a), administrative regulations are invalid if there is a "substantial failure to comply with this chapter," i.e. the requirements for regulatory rulemaking set out in Government Code §11340 *et seq.*, California's Administrative Procedure Act ("APA"). The following provides additional examples of how DTSC has substantially failed to comply with the APA. This is not an exhaustive list as the lack of clarity, and inconsistencies or conflicts with the controlling statute are also failures of DTSC to comply with the APA.

- a. Consistency – A regulation may be held invalid if it is inconsistent with a dictate or provision of the governing statute. *Sabastasso v. Superior Court* (2008) 167 Cal. App. 4th 791, *Morris v. Williams* (1967) 67 Cal. 2nd 733, *Slocum v. Board of Equalization* (2005) 134 Cal. App. 4th 969, *Pulaski v. California Occupational Safety and Health Standards Board* (1999) 75 Cal. App. 4th 1315. In addition, a statute may be held invalid if it is found to be inconsistent with the purpose of the governing statute. See, *Clean Air Constituency v. California Air Resources Board* (1974) 11 C.3d 801, 815, *Alford v. County of San Diego* (2007) 151 Cal.

App. 4th 16, *Rosas v. Montgomery* (1970) 10 Cal. App. 3d 77, 92. In addition to well established case law, this is also DTSC's requirement under Government Code Section 11342.1 "Each regulation adopted, to be effective, shall be within the scope of the authority conferred and in accordance with standards prescribed by other provisions of law." Also, Government Code Section 11342.2. then provides, "no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute."

- i. Section 69506. Regulatory Response Selection Principles: Subdivision (a) provides that the Department shall identify and require implementation of regulatory responses that "maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible." Subdivision (b) provides that in selecting regulatory responses, the Department shall give preference to responses "providing the greatest level of inherent protection." Inherent protection is defined to mean "avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls." These provisions of section 69506 seem to conflict with the statutory provision in section 25253. There, the Legislature has established the standard for evaluating chemicals of concern in consumer products and their potential alternatives "to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." Limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection.
- ii. Section 69506.12. Regulatory Response Report and Notifications. This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. The balance of this section sets out when and how that notification is to be provided. A substantial question exists as to whether this requirement is authorized by the statute. Section 25253(b) of the statute provides that the regulations adopted pursuant to this section shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. The notification to the retailers is not designated as a regulatory

response. Rather, it is applied to a responsible entity after a regulatory response is imposed on that entity. Nothing in the statute authorizes the Department to impose such a reporting requirement. It exceeds the scope of the authority to specify the range of regulatory responses.

- b. DTSC Improperly Issued a California Environmental Quality Act ("CEQA") Notice of Exemption (DTSC 1332 (03/04/08)).
- i. The points made about review and multimedia evaluation in the GCA Letter dated October 26, 2010 continue to be relevant and are incorporated herein. See attached. DTSC and the Council continue to ignore the requirement to consider and address any and all adverse impacts that may be the unintended result of the Proposed Regulations.
 - ii. CEQA broadly applies to an agency's discretionary approval of a project, which includes adoption of regulations that may have a significant impact on the environment. Public Resources Code ("PRC") § 21080; 14 Cal. Code Regs. ("Guidelines") § 15357.¹ DTSC has failed to assess the negative environmental impacts that will likely result from implementation of the Proposed Regulations. *Building Code Action v. Energy Resources Conserv. & Dev. Comm'n.* (1980) 102 Cal.App.3d 577 (overturning energy conservation standards for windows because resulting increase in glass production could have significant air quality impacts). DTSC indicates in the Notice of Exemption that the Proposed Regulations are exempt under the "common sense" exemption. The common sense exemption applies when "there is no possibility that the activity in question may have a significant effect on the environment." Guidelines §15061(b)(3). There is no implied finding that the Regulations are exempt and DTSC is required to "provide the support for its decision before the burden shifts to the challenger" thus "[i]f a reasonable argument is made to suggest a possibility that a project will cause a significant environmental impact, the agency must refute that claim to a certainty before finding that the exemption applies." *Davidon Homes v. City of San Jose* (1997) 54 Cal. App 4th 106, 117- 118 (emphasis in original). DTSC's explanation provided for the "common sense" exemption does not satisfy the burden of proving that there will be no

¹ *Plastic Pipe & Fittings Assn. v. California Building Standards Com.* (2004) 124 Cal.App.4th 1390, 1412 ("A regulation fitting the description of a discretionary project is a discretionary project under CEQA." (citing *Wildlife Alive v. Chickering* (1976) 18 Cal.3d 190, 206; PRC §21000(g).)

significant environmental impact. Provided below are examples of significant environmental impacts that are potential unintended consequences of implementation of the Proposed Regulation.

- iii. DTSC also argues that it could not conduct environmental review at this stage because any potential impacts are too speculative and the CEQA analysis should not be conducted until later in the process. Notice of Exemption, Page 6. CEQA Guidelines advise that "[w]hile foreseeing the unforeseeable is not possible, an agency must use its best efforts to find out and disclose all that it reasonably can" and "[i]f, after thorough investigation, a Lead Agency finds that a particular impact is too speculative for evaluation, the agency should note its conclusion and terminate discussion of the impact." Guidelines § 15144, 15145 (emphasis added). Here, DTSC has not used its best efforts to make a thorough investigation and instead has simply deferred environmental review to a future date. However, future environmental review does not excuse DTSC from adequately analyzing reasonably foreseeable significant environmental effects of the project and does not justify deferring such analysis to a later environmental review document. As demonstrated by the examples below and those submitted by other commenters, if DTSC investigated the issue, it would find there is substantial evidence of knowable potential impacts, even at this stage in the regulatory process. The examples below demonstrate a more than reasonable argument that there will be potential environmental impacts, which can and must be analyzed now. Indeed, there are a myriad of examples of agencies reviewing regulatory actions. Some examples are the Bay Area Air Quality Management District Thresholds for Greenhouse Gas Emissions and Toxic Air Contaminants and the Air Resources Board's Functional Equivalent Document for the Assembly Bill 32's Scoping Plan and the 33 Percent Renewable Electricity Standard. Just as in those examples, DTSC can and must review the environmental impacts of the Proposed Regulations.
- iv. Examples of significant environmental impacts of the Proposed Regulations that DTSC should assess include the following:
 1. The inability to completely control a recycled material stream coupled with the detection level AA Threshold will cause companies to avoid using recycled materials even before COCs are selected. One example is paper products currently utilizing recycled content. Many paper products incorporate significant

levels, and up to 100%, post-consumer recycled fiber. It is virtually impossible to know in advance what chemicals may be present as contaminants with the collected wastepaper used as the post-consumer raw material for these products. The recycling processes remove and/or significantly reduce those contaminations but the finished product may still retain some low level contaminants which do not impact the safety or efficacy of the finished product but may trigger AA review if there is no consideration of threshold limits for these unintentional contaminants. As an example it is believed that ATM and some cash register receipts may contain trace amounts of bisphenol A (BPA). If BPA is selected as a CoC and paper products (packaging, copy paper, cardstock, etc.) are chosen as priority products, this could lead to a decrease in the use of recycled content, thereby increasing the need to use virgin paper pulp sources. Any program that has the potential to reverse the progress that has been made for collecting and recycling recover wastepaper needs to be very carefully considered since it will be contrary to all the various efforts and legislations by the State and County jurisdictions to increase recycled content in paper products and move toward zero waste going to landfills. A decrease in the removal or diversion of wastepaper from the solid waste stream will most likely increase its flow back to the landfill. This would be an unacceptable consequence if not properly addressed.

2. Companies will desire purer virgin feedstock; this will require greater energy to produce and lead to greater waste. An example of this are the plastics used to make ink cartridges. Currently some manufacturers utilize reclaimed cartridges combined with reclaimed PET to make new cartridges. (See HP example: <http://www.hp.com/hpinfo/globalcitizenship/environment/productdata/recycledcontentink.pdf>) This currently keeps both water bottles and used ink cartridges out of landfills. If DTSC were to select carbon black, a commonly used colorant in inks, as a chemical of concern and there was the possibility that trace amounts of the carbon black may end up in the recycled content of the mixture to make new cartridges, this would encourage companies to use virgin plastics instead of finding creative ways to used closed loop recycling to produce new products. The

resulting significant environmental impact would be increased disposal of used ink cartridges and plastic bottles into landfills, and increased energy used to create the plastics for the new cartridges.

3. Section 69506.4(b)(2)(A): This section requires manufactures to provide information on the product packaging or in accompanying written material accessible without breaking the product seal. This inherently would require an increase in product packaging and/or posting of additional signage at point of sale. Increasing the packaging and signage will have the unintended consequence of contributing to increased waste and energy to produce the information materials as well as increase the amount of waste from an increased amount of used packaging.
4. Informed consumer behaviors may have significant environmental impacts. Compact Fluorescent Lights (CFL) are very energy efficient but contain measureable amounts of mercury. One alternative to the CFL is the traditional incandescent light bulb. However, the federal government in 2007 decided that energy efficiency was more important that the small amounts of mercury that may be in CFL's when they enacted the Energy Independence and Security Act of 2007 (EISA 2007). Under this law, light bulbs are required to be about 25 percent more efficient. In California, new lighting standards will eliminate traditional 40 and 60 W incandescent light bulbs as of January 1, 2013. See, California Department of Energy FAQ http://www.energy.ca.gov/lightbulbs/lightbulb_fags.html. Therefore, due to the mandates that have been made around energy efficiency, the DTSC Proposed Regulations could have the unintended consequence of eliminating yet another lighting option for consumers in California due to chemical restrictions.
5. Research and Development (R&D) looking at new ways to use existing chemicals would also be stifled due to the COC listings. Researchers looking for innovative new formulations to make products last longer, function in different or improved ways or to enhance other environmental characteristics will be discouraged from looking at any of the COCs listed on DTSC's list. In the research and development (R&D) sector, the individuals handling materials are far more experienced and knowledgeable in the safe

experimental use of chemical substances than the DTSC. It is an unreasonable and illogical assumption of DTSC to restrict use by qualified individuals familiar with risks and proper disposal methodology. Outside of the industry there are additional consequences to a lack of an R&D exemption. Companies manufacture and sell chemicals and reagents used for primary research (examples include ThermoFisher Scientific, Bio-Rd, Sigma-Aldrich). If these companies can no longer sell some of their products in a California market, it is possible that research institutions developing drugs for treatment of disease, for example, no longer will be able to do research in California. This would potentially cause experimental inconsistency, in that groups may not have the option of looking for alternative products because previous experiments against which comparisons are made or conclusions drawn did not use that same product. It is unclear whether DTSC has reached out to the academic or private research community to better understand the potential downsides of the failure to include an R&D exemption. The potential for a loss in millions of dollars of research grants could have an enormous impact on the California economy and California institutions performing R&D.

VI. DTSC has Failed to Include a Robust Economic Analysis

Please see Attachment 2 for our analysis and concerns with DTSC's economic analysis provided to support the Proposed Regulations.

Attachment 2
October 8, 2012

Comments on DTSC’s Economic and Fiscal Impact Statement and Economic Analysis

The DTSC is required to file a Std. Form 399 - Attachment to the Economic and Fiscal Impact Statement for proposed regulations.

The statement as filed by the DTSC for the Safer Consumer Products Regulation is inadequate and devoid of any substantive information. The recurring theme throughout the document is that the economic and fiscal impact of the proposed regulation will only be quantifiable after the regulation is implemented and operating. Given that the DTSC has afforded the Proposed Regulations “landmark” status, the document is even more inadequate. The DTSC appears to have failed to even attempt to provide any meaningful data, choosing instead to rely on the document “*Economic Analysis for California’s Green Chemistry Regulations for Safer Consumer Products*” prepared by Matthew E. Kahn for the economic analysis. A careful review of this document reveals that Mr. Kahn’s analysis is based on a biased and largely unsubstantiated perspective. An analysis of Mr. Kahn’s document follows.

Overall Comment

The entire tone of the economic analysis negatively portrays industry with unsubstantiated generalizations that characterize industry as “profit seeking” with “agendas” that do not align with the spirit and intent of the regulations. Much of the economic and social benefits that are purported to arise from the implementation of the Proposed Regulations are based on the supposition that industry does not currently take responsibility for the composition and safety of its products. That assumption is just not accurate.

“New Rules of the Game”

Numerous times throughout the economic analysis, there is reference to the phrase “new rules of the game.” It is suggested that it is not already incumbent upon manufacturers to manufacture products that are safe for their intended use and to provide hazard information to consumers. There is a supposition that through regulation this will now be realized. The concept of manufacturing products safe for their intended use is not a “new rule” to industry. What will be new to industry is a regulatory framework that allows regulators to arbitrarily choose the winners and losers in the marketplace under guise of protecting public health. The regulation, in fact, provides many rules for manufacturers, yet provides for very few rules for the regulators who are given unfettered authority to determine what is compliant and “safer” and what is not.

On page 27 of the report the author makes the following statement.

“The DTSC has anticipated that the regulated firms and the regulator may not have aligned incentives. The DTSC will hope that firms hire the best assessor in judging the firm’s options. In contrast, the firm may seek out consultants who are low cost and have a reputation for embracing the firm’s agenda.”

The justification for this statement is unknown as it receives no further discussion or substantiation in the document. The statement appears to be an editorial comment and one which is inappropriate and not germane to an economic analysis of the Proposed Regulation. The certified assessors as identified in the regulation are required to be “certified” based on their knowledge, expertise and experience in the subject matter and not because of a particular bias or agenda. The tone and implication of the statement is further evidence of an economic analysis that was constructed on a false, biased and unsubstantiated premise that industry does not care about the safety of its products.

Closing the “Information Gap”

There is an overwhelming tone within the text of the analysis that is generally condescending toward industry. There is a supposition that manufacturers of both consumer products as well as ingredient/component manufacturers know little about the composition of the products they make. The term “profit-seeking” is used as adjective to describe manufacturers as though having this objective is mutually exclusive with manufacturing products that are safe for their intended uses. This is an extreme generalization of the manufacturing industry that is biased, unfair and unsubstantiated. There is an assumption that there will be economic benefit to the State of California and consumers if industry is forced to understand the composition of their products better than they do today as a result of the Proposed Regulations. This is an unsubstantiated assumption. Most manufacturers already have a good understanding of what is in their products and use this information to provide information to consumers for the safe handling and use of the product. We fail to see the economic benefit of closing this perceived information gap regarding composition. Information that identifies and communicates the hazards of and how to safely handle products is what protects consumers. This unsubstantiated benefit should not be included as an economic benefit as it is already the industry norm.

It is presumed that information from a “trusted source” will drive consumers to change their behaviors. Based on established consumer behavior, the presumption that more information about product composition will change consumer behaviors is false. As an example, despite the warning labels on products such as cigarettes and alcohol as well as the widespread awareness that many fast foods are unhealthy, consumers still use and/or consume all of these products. Furthermore, where substantial compositional and hazard information is made readily available to consumers through product and point of purchase labeling and public education programs, consumers make unhealthy choices despite the wealth of information that is available to them.

Inclusion of Workplace Exposures in Scope of Regulation

The scope of the Proposed Regulation has been expanded inappropriately to encompass workplace exposures. However, there is only one sentence that clearly discusses any economic benefits (pg 37) that will result from this expansion of scope. The benefits are not related to exposure to consumer products while using them in the workplace. Instead, they are focused on potential exposures during the upstream manufacture of the consumer products and no explanation of the economic benefits subjective or otherwise are stated. We believe this is in large part due to the fact that these benefits are already driven by existing occupational health and safety regulations that address this concern. As such, this inclusion of workplace exposures in the Proposed Regulation is redundant and duplicative with existing obligations to prevent workplace exposures to hazardous chemicals and to warn workers of the hazards of the products they encounter in the workplace. Furthermore, this inclusion of workplace exposures will yield no economic benefit, because the protections already exist.

The U.S. Occupational Safety and Health Administration's Hazard Communication Standard (29 CFR 1910.1200) requires companies to provide workers with information on chemicals used in the workplace, training on the handling of and protection from chemicals, as well as information on chemicals present and labeling of such chemicals. It is therefore inaccurate for the analysis to assume that workers have little knowledge of the chemicals in their workplace, and that, as a result, there is economic benefit from the implementation of the Proposed Regulation.

Proposed Regulation Will Not Foster "Capitalist Competition"

The analysis suggests that firms that are nimble enough to identify alternative "green" products through innovation will thrive and capture in a high rate of return on their investment. However, the transparency that is required by the Proposed Regulations will result in those innovative firms disclosing their intellectual property to existing and future competitors. Intellectual property and innovation will become community property, and the company's return on innovation will be marginalized. This is a negative incentive to being first to market with any alternative.

The economic analysis is further flawed by downplaying the likelihood that the loss of trade secrets will occur by suggesting it is a low probability event. There are significant information disclosure requirements that can include highly competitive information about manufacturing processes and product composition. Information that must be disclosed will do little to benefit the public and much to benefit existing and future competitors. Intellectual property protection is a real business concern, not a hypothetical one. Intellectual property is highly competitive, and intellectual property disputes are vigorously litigated as is illustrated by the recent *Apple Inc. v. Samsung Electronics Co. Ltd.*, 11-cv-01846, U.S. District Court, Northern District of California (San Jose). Transparency must be confined only to that information essential to address the public safety and environmental impacts of the products and balanced with protection of confidential business information to prevent the loss of IP, including trade secrets, and avoid stifling innovation. We agree

with the author's assertion that loss of trade secret information would be very costly for firms. However, we do not agree it is a low probability event. Nor do we agree that there are substantial trade secret protections afforded by the Proposed Regulations.

In a competitive market environment, competitors will not be interested in forming "clubs" or trade associations to identify alternatives particularly in markets that are highly competitive and that depend on maintaining their trade secrets to be competitive. The suggestion that this is one way the industry can mitigate its short run vs. long run costs to comply is not realistic. It is highly unlikely that competitors could form consortiums to develop alternative products without being perceived as engaging in anti-trust activities. Principled manufacturers would seek to avoid even the appearance of such behavior.

It is suggested that regulatory responses to fund green chemistry grants will be a way to provide funding to smaller firms to conduct research and development of "green" alternatives. This is yet another provision within the regulation that is counterintuitive to the premise that this will somehow foster market based competition. Those firms who preferentially receive government funding will have an unfair and non-market based advantage over those firms who do not. Furthermore, it suggests this regulatory response will be a way that the regulation will be able to foster innovation. This provides yet another mechanism for regulators to pick the winners and losers.

Higher Short Run Costs Justified Based on Lower Long Run Costs

The economic analysis suggests that higher short run costs are justified by lower long run costs. What it has failed to acknowledge is that companies that cannot tolerate the short run financial impact will not benefit from lower long run costs, because they will no longer be in business. They will be forced to abandon the California market or possibly discontinue their business altogether.

In the Executive Summary, contradictory statements are made with regard to the potential impacts to California employment. It is suggested that short run costs will be minimal since most product manufacturing takes place outside of California. In the next paragraph, it suggests that California firms will have an advantage in gaining market share. If most manufacturing takes place outside of California, it is unclear how the Proposed Regulations will make it possible for companies to be able to gain market share in California or Europe, as is also suggested in the economic analysis. The potential negative impact on the economy will be felt in California as well as other states when smaller companies are not able to invest the resources to comply with such an onerous regulation.

Social Benefits Are At Risk Based on Proposed Regulation

Section 6 of the economic analysis indicates that the essential factors in realizing the social benefits of the Proposed Regulations are: 1) how well DTSC prioritizes chemicals, 2) how many Priority Products

DTSC identifies and how quickly they do so, 3) how motivated firms are to test their products and develop safer alternatives, and 4) whether consumers will use the new risk information to reduce exposures.

Unfortunately, none of these key factors are well conceived within the proposed regulation. There is insufficient clarity for how DTSC will prioritize chemicals and identify priority products. The author himself made the following statement when discussing those key factors relative to job impact.

“Given the fundamental uncertainty about the details of how DTSC will implement the regulations in terms of choosing priority products and the decisions it will make in the alternatives analysis, it is impossible to offer precise predictions concerning how California jobs will be affected.”

The “fundamental uncertainty” he references applies to all aspects of the purported benefits, including the social benefits. Furthermore, for the numerous reasons outlined above, the regulation creates a negative incentive that will hinder the development of safer alternatives. Finally, as detailed above, consumers do not have a track record of making “healthier” choices to reduce exposures even when provided information about the risks of the products available to them. The economic analysis presumes that the information being provided to consumers today is insufficient and that the huge volume of highly technical and complex information proposed to be provided will somehow simplify and enhance their current level of decision making. The author failed to provide any compelling or substantiated evidence to support this presumption. As a result, it is unlikely that any true societal benefits will be realized as well as any corresponding economic benefits that could result from them.

The assertion that “AB 1879 draft regulations reduce the likelihood of local communities near landfills suffering from toxic pollution” appears to make the assumption that leakage and contamination from landfills is a likely scenario. Landfills, however, are subjected to rigorous design restrictions, zoning and permitting, and monitoring regulations established by the U.S. EPA and the State of California. Although there may be a remote chance of landfill leachate contaminating the groundwater, the assumption that this regulation will reduce that risk is inaccurate and unsubstantiated and does not support the conclusion that any societal benefit or economic benefit will result.

Flawed Comparisons Between the Proposed Regulation and REACH

Throughout the economic analysis, parallels are drawn between the Proposed Regulations and the European REACH framework (the EU regulation Registration, Evaluation, Authorisation and Restriction of Chemical Substances (EC 1907/2006) referred to herein as “REACH”). It is suggested that alternatives to existing products will be available from manufacturers who are complying with REACH which will

result in negligible impacts to consumers in terms of the availability of alternatives to products that must be phased out under the Proposed Regulations. This demonstrates a clear lack of understanding on the part of the author concerning the REACH regulation as implemented and the Proposed Regulations as drafted and negates any mitigation of the economic impacts of the Proposed Regulations that rely upon these flawed assumptions. The flaws in this conclusion include (but are not limited to) the following:

- Chemicals that are present in the product but do not contribute to the hazard of the product do not drive restrictions or bans of the product under REACH. If a component, impurity or otherwise, is present but does not influence the outcome of the classification, it is not regulated. In Europe, 1.0% and 0.1% de minimis concentrations are applied. Conversely, the Proposed Regulations give the regulators the latitude to set concentration limits on a case-by-case basis which leaves open the possibility for those limits to be set lower. As such, the assumption that REACH compliance will equal compliance with the Proposed Regulations is incorrect as is the assumption that this somehow would mitigate the economic impact of the Proposed Regulations for California consumers and retailers.
- Compliance with the Substance of Very High Concern (SVHC) provisions of REACH does not automatically exclude presence of SVHCs or candidate SVHCs in consumer products. The only obligation to comply (related to SVHC) in the case of the import of articles into Europe is to provide information to the consumer about the presence of the SVHC upon request if the SVHC is at levels > 0.1%. The same obligation applies to the manufacture of articles containing candidate SVHCs.
- Only EU manufacturers of articles containing an SVHC (hence the users of the SVHC) are required to obtain an authorization for that use. This creates an advantage for non-EU manufacturers of articles containing SVHC substances, as they do not have to apply for an authorization to use the SVHC, and furthermore, they can freely import the SVHC containing article into the EU.
- The REACH framework allows for the demonstration of negative exposure even where a SVHC may be known to be present in a finished article. This is in stark contrast to the Proposed Regulations where the mere presence of a substance in a product is presumed to result in exposure and triggers an alternatives analysis.
- The analysis also includes a presumption that “drop in” alternatives are readily available from within the European market. However, polymers and articles, common components of consumer goods, are not directly regulated under REACH so they would not have the same safety standard applied to them. Within the REACH framework, there is shared responsibility for compliance where the end user is responsible for ensuring their use is consistent with the way the product has been registered. This allows for establishing safe use conditions that are

communicated to end users in order to mitigate their risk of exposure to the substances in the product. The Proposed Regulations fail to provide any provision for this shared responsibility concept that has been incorporated into REACH which plays a significant role in mitigating human health and environmental exposure concerns.

- The exposure and risk assessments under REACH try to determine what the exposure is and what the risk is likely to be over the life cycle of the product. If that is found to be acceptable, there is no reason not to include hazardous substances into articles used by consumers. In this regard, REACH is a risk based approach vs. the strictly hazard based approach that is contemplated by the Proposed Regulations.

Throughout the economic analysis, many comparisons are made between the Proposed Regulation and REACH. The Executive Summary suggests there is empirical support for the claim that the time allowed for firms to adapt to the new regulation provides for lower regulatory compliance costs. However, the empirical support for this is not discussed elsewhere in the analysis. The author failed to provide any examples of instances where firms have innovated in ways that lead to a lower cost of compliance through the introduction of alternative products. Additionally, so few chemicals have been through the SVHC process thus far that could have resulted in direct impacts to consumer products that this appears to be a speculative extrapolation rather than a fact-based hypothesis.

For example, in the case of a product that must be phased out, the manufacturer of the incumbent product will lose profit and business while the manufacturer making the replacement will win. The user will switch from one to the other – if he is lucky, at same cost and performance. The potential benefit to society will be if that change reduces mortality, illness, environmental impacts, etc. However, there is no lower compliance cost in this instance. In fact, compliance costs will rise including the time that will be spent managing supply chain communications whether chemicals of concern are present in products or not. Onerous alternative assessments that are not currently required will drive added compliance costs. Identifying and implementing alternatives for hazardous substances that do not present an actual risk in a finished product is a waste of resources rather than a saving of compliance costs.



Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

October 26, 2010

Alliance of Automobile
Manufacturers

American Chemistry Council

American Forest & Paper
Association

California Chamber
of Commerce

California League of Food
Processors

California Manufacturers
& Technology Association

California Paint Council

California Restaurant Association

California Retailers Association

Can Manufacturers Institute

Chemical Industry Council of
California

Citizens for Fire Safety Institute

Consumer Healthcare Products
Association

Consumer Specialty Products
Association

Grocery Manufacturers
Association

Industrial Environmental
Association

Metal Finishing Associations of
Northern and Southern CA

National Paint and Coatings
Association

Personal Care Products Council

Plumbing Manufacturers Institute

Soap & Detergent Association

TechAmerica

Toy Industry Association

Western Plant Health Association

Western States Petroleum
Association

VIA EMAIL AND REGULAR MAIL

Secretary Linda S. Adams, Chair
Environmental Policy Council
1001 I Street, P.O. Box 2815
Sacramento, California 95812
cepc@calepa.ca.gov

Re: Comments for October 27, 2010 CEPC Hearing - On the Need for the CEPC to Review a Multimedia Evaluation of DTSC's Safer Consumer Product Alternatives Regulations

Dear Secretary Adams:

On behalf of the Green Chemistry Alliance we appreciate this opportunity to provide comments on the need for the Environmental Policy Council to review a multimedia evaluation for the Green Chemistry Safer Consumer Product Alternatives Regulations pursuant to California Health and Safety Code Section 25252.5. As discussed below, Council review of a full multimedia analysis is critically important to ensure that all adverse impacts to public health and the environment are considered in the creation of this groundbreaking new regulatory framework.

The Green Chemistry initiative in California represents a sea change in the regulation of toxins in our environment. In 2008, the California Legislature passed "Green Chemistry" legislation intended to reduce toxic chemicals in products. Unlike previous laws which focused on regulating pollution from facilities, the new Green Chemistry law regulates *products* sold in California. The Legislature directed DTSC to draft regulations to implement the groundbreaking new law, and on September 14, 2010 DTSC released its draft Green Chemistry Regulations. These sweeping regulations would likely cover thousands of chemicals, which are likely to be found in tens of thousands of products.

Recognizing the far-reaching impact of the new law, the Legislature also directed DTSC to conduct, as part of its rulemaking process, a multimedia evaluation of adverse impacts the proposed regulations could have on public health or the environment. Thus, in its effort to comprehensively regulate products sold in California to keep consumers of those products safe, DTSC must also consider the possible impacts such expansive regulations could have on other media such as air, water, waste disposal, or public health. The Legislature did not leave responsibility for this important holistic analysis to DTSC alone, however, but specifically drafted the new law to expand the role of the Environmental Policy Council, thereby enlisting the expertise of

the directors of the state's key environmental agencies. This legislative expansion of the Council's role is almost unprecedented, having occurred only once in the Council's nearly 20-year existence.

Despite the Legislature's express direction that the Council consider potential adverse impacts from this far-reaching, largely unprecedented new regulatory scheme, DTSC now recommends that instead of taking a close look, the Council should simply accept DTSC's determination that the process could not possibly result in significant adverse impacts to public health or the environment. DTSC's recommendation appears to be based on the premise that the regulations are intended to benefit public health and the environment, so therefore they could not have an adverse impact and a multimedia review is not required.

The question for the Council, however, is not whether the regulations will do more harm than good. Instead, the Council's legislatively mandated task is to help DTSC consider and address any and all adverse impacts that may be the unintended result of these regulations. This is a historic mandate by the Legislature to the Council. The Council cannot fairly and legally carry out this mandate by making a determination based solely on DTSC's cursory summary and review of its own regulations. Moreover, as a matter of public policy the Council should not simply take a pass, but should instead fulfill the purpose for which the Council was created by providing the agencies, industry, and public with the benefit of Council members' unique ability to provide a holistic review and refinement of these landmark regulations.

Conclusion

Even though the proposed regulations are designed to benefit public health and the environment, they may result in significant adverse impacts. These significant adverse impacts may be offset by benefits, but cannot be discounted by the Council when making a determination whether there is any possibility of a significant adverse impact. In other words, the Council cannot conclusively determine that the proposed regulations will not, in any way, adversely impact public health or the environment. The Legislature required that the Council conduct a thorough review of the process put in place by DTSC intended to reduce public health and environmental impacts from chemicals. We ask that the Council fulfill its role in this vitally important process. A full multimedia review will allow EPC, DTSC and the public to become better informed about the options available to DTSC to implement the Green Chemistry laws.

Thank you again for this opportunity to comment.

Sincerely,



John R. Ulrich
Co-Chair
Chemical Industry Council of California



Dawn Sanders Koepke
Co-Chair
McHugh & Associates

CC: Cindy Tuck, Undersecretary, CalEPA
Patty Zwarts, Deputy Secretary, CalEPA
Maziar Movassaghi, Acting Director DTSC
John Moffatt, Legislative Affairs, Office of the Governor
Scott Reid, Cabinet Secretary, Office of the Governor
The Honorable Joe Simitian, California State Senate
The Honorable Mike Feuer, California State Assembly



California New Car Dealers Association

October 11, 2012

Ms. Deborah Raphael
Director
Department of Toxic Substances Control (DTSC)
P.O. Box 806
Sacramento, CA 95812-0806

RE: PROPOSED SAFER CONSUMER PRODUCTS REGULATION

Dear Director Raphael:

The California New Car Dealers Association (CNCDA) is a statewide trade association which represents the interests of over 1,300 franchised new car and truck dealer members. CNCDA members are primarily engaged in the retail sale of new and used motor vehicles, but also engage in automotive service, repair, and parts sales. We are writing to provide comments and suggested solutions to issues raised by the proposed “Safer Consumer Product Alternatives” (Green Chemistry) Regulations.

CNCDA has actively participated in commenting on the Green Chemistry Regulations since before the initial draft Regulations were circulated in 2010. We have supported the development of a science-based process to improve the safety and reduce the environmental impact of consumer products in California, but have had significant concerns with previous drafts due to the burdens those proposals placed on California dealers and other retailers. While the currently proposed regulation marks an improvement from previous drafts, CNCDA still has procedural and policy concerns with several provisions. Our concerns and comments primarily revolve around three central themes, and are organized accordingly:

- Ensuring that dealers and other non-manufacturers and non-importers are not subject to the substantive requirements of the regulation;
- Ensuring that dealers have access to products, replacement parts, and supplies sufficient to maintain and service customer vehicles; and
- Ensuring that any regulatory responses the Department may take concerning consumer products will be predictable, reasonable, and possible to implement.

Each comment described herein also contains suggested amendments to address our concerns. We appreciate this opportunity to provide comments and suggestions to the Department and look forward to continuing to work with the Department on amendments.

STANDARD OF REVIEW

Throughout the regulatory proposal, the Department cites Health and Safety Code Sections 25252, 25253, and 58012 as authority to implement the proposed regulations. Health and Safety Code Section 25252 and 25253 require the Department to adopt regulations to establish the Green Chemistry Program. Uncodified Government Code Section 58012 provides the Department with general authority to adopt regulations for the execution of its duties. None of the sections cited as authority for the regulatory proposal exempt the Department from the requirement to comply with the Administrative Procedures Act (APA).¹ The APA was passed in 1979 with the intent of creating explicit and stringent standards for regulatory approval that apply to *any* exercise of quasi-legislative power granted by statute—and specifically states that the requirements “shall not be superseded or modified by any subsequent legislation except to the extent that the legislation shall do so expressly.”²

With the goal of reducing the number and complexity of regulations, the APA requires that every regulatory proposal must adhere to six standards for approval by the Office of Administrative Law (OAL). The standards are: Necessity; Authority; Clarity; Consistency; Reference; and, Nonduplication. As described in these comments, the Department’s regulatory proposal fails to meet several of these requirements, most notably those requirements summarized as follows:

Authority and Reference – As discussed above, the APA requires the regulatory agency to cite a provision of law that permits the agency to adopt, amend, or repeal a regulation (authority) and to cite a statute that the agency seeks to interpret or make specific (reference). Although all agencies are given some general authority to implement regulations through some statute (e.g. Health and Safety Code Sections 25252, 25253, and 58012), such general enabling statutes do not grant regulatory agencies with *carte blanche* power to expand upon the legal provisions being implemented.

The regulations adopted by the OAL recognize that while an administrative agency’s interpretation of its rulemaking authority is generally presumed conclusive, this is not the case when either a public comment challenges such authority, or the agency’s interpretation of its authority “alters, amends or enlarges the scope of power conferred upon it.”³ This regulation restates a long history of judicial precedent, *see, e.g., Crees v. California State Board of Medical Examiners*.⁴ In *Crees*, the Appellate Court upheld a decision striking down a regulation

¹ Government Code Sections 11340, *et seq.*

² Government Code Section 11346(a)

³ 1 California Code of Regulations 14(c)(1).

⁴ (1963, Cal App 2d Dist) 213 Cal App 2d 195. The California Supreme Court denied Appellants petition for hearing in 1963. *See also* Whitcomb Hotel, Inc. v. California Employment Com., 24 Cal. 2d 753, 1944 Cal. LEXIS 276 (Cal., August 18, 1944);

expanding upon the definition of Chiropractic practice “as it purported to alter or enlarge the scope” of the enabling statute. Demonstrating the established lineage of this authority requirement, the *Crees* court quoted other notable decisions stating that “an administrative officer may not make a rule or regulation that alters or enlarges the terms of a legislative [or initiative] enactment,”⁵ and that “[a] regulation, . . . insofar as it attempt[s] to enlarge the terms of the enabling statute, . . . is invalid.”⁶

Necessity – The APA requires administrative agencies to adhere to two separate necessity standards under the APA. First, Government Code Section 11342.2 requires that regulatory language be “reasonably necessary to effectuate the purposes of the statute” being implemented. Accordingly, a regulatory agency is prohibited from implementing a regulation not necessary to realize the explicit legislative intent of the statute.

Government Code Section 11349.1 introduces a second necessity standard, requiring that the rulemaking record demonstrates, by substantial evidence, the need for a regulation to effectuate the purposes of the statute being implemented. To meet this requirement, the Department must include in a statement of purpose for each adoption or amendment, information demonstrating not only that each provision is required to effectuate the purpose of the statute at issue, but also that there exists, factually, a need for each provision.⁷

Clarity – Regulations must be written in a manner such that they will be easily understood by persons directly affected.⁸ A proposed regulation violates this standard if it can “be reasonably and logically interpreted to have more than one meaning,” or “the language of the regulation conflicts with the agency’s description of the effect of the regulation.”⁹

Consistency – As with the Necessity standards discussed above, two separate Consistency requirements apply to a regulatory proposal. First and foremost, Government Code Section 11342.2 states that “no regulation adopted is valid or effective unless consistent and not in conflict with the statute.” Second, a regulatory proposal must be “in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.” This requirement applies in particular to the enabling statute a proposed regulation purports to implement.

ALLOCATION OF COMPLIANCE BURDENS

Proposed Section 69501.2 clearly expresses the Department’s intent that manufacturers

⁵ *People v. Mangiagli*, 97 Cal.App.2d Supp. 935, at 943.

⁶ *Duskin v. State Board of Dry Cleaners*, 58 Cal.2d 155, at 165.

⁷ 1 California Code of Regulations 10.

⁸ Government Code Sections 11349 and 11349.1. 1 California Code of Regulations 16 further defines those being “directly affected” to include persons legally required to comply with the regulation.

⁹ 1 California Code of Regulations 16.

bear the primary and importers the secondary burdens of compliance with the substantive requirements of the regulation. This section goes further and states that a retailer need only comply with the regulation after the manufacturer and importer fail to comply with a mandate, and the Department provides specific notification to retailers that they must either stand in the place of the manufacturer/importer or cease ordering a product that is subject to the compliance burden. While this section appropriately allocates compliance burdens upon the entities responsible for manufacturing or bringing a consumer product to California, other key provisions of the regulatory proposal obstruct this intended allocation of responsibility. Getting these provisions correct is crucial—saddling the inappropriate party with responsibility to submit technical information or perform Alternative Analysis when unable to do so could cause devastating economic and legal liability for that party, and do absolutely nothing to improve the safety of consumer products.

1. “Import” Definition §69501.1(a)(35)

The Proposed Definition of “Import” is Overbroad and Lacks Clarity – The proposed regulation defines “Import” as “to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce.” This definition directly ties into the definition of “importer” pursuant to proposed §69501.1(a)(36), and (pursuant to proposed § 69501.2(a)) effectively allocates the secondary burden of compliance with the Green Chemistry Regulations on any person who performs an activity covered under the definition of “import.” The proposed definition encompasses a wide range of activities not normally considered importation, and would subject many unintended parties to the Green Chemistry Regulations.

The problem manifests itself clearly in context of the retail new vehicle industry: dealers franchised to sell vehicles manufactured outside of the United States are (and appropriately should be) generally considered as retailers under the Green Chemistry Regulations, but perform activities that would be considered importation under the proposed definition. For example, a California Toyota dealer (DTSC Toyota) may contact Toyota’s California-based United States distributor, Toyota Motor Sales, to purchase 50 new Toyota Corollas for resale; Toyota Motor Sales will then cause 50 Toyota Corollas to be manufactured in Japan and delivered to the DTSC Toyota. DTSC Toyota, by arranging to have vehicles brought into California from another country for retail sale, would clearly be considered as “bring[ing], or arrang[ing] to bring a consumer product into the United States for purposes of placing the product into the stream of commerce” and therefore be considered as conducting import activities.

Since many “foreign” automakers maintain manufacturing facilities within the United States, and every “domestic” automaker maintains manufacturing facilities abroad, the proposed definition could conceivably result in every franchised new vehicle dealer located in California performing “import” activities and therefore meeting the definition of “importer”—at least for

some vehicles and parts—despite the fact that they place orders through distributors located in the United States (several within California).

Highlighting the overbreadth of this definition, a *consumer* will often sit down with a dealer to order a vehicle that meets certain characteristics, after which the dealer will order the vehicle from the distributor, who will in turn cause the vehicle to be manufactured and delivered within California. Has this consumer conducted “import” activities by “arranging to bring” a foreign-manufactured product into the United States? The proposed definition could result in THREE importers for the product—the consumer who ordered the vehicle from the retailer, the dealer who ordered the vehicle from a United States distributor, and the United States distributor itself.

In reality, the United States distributor should be the party responsible for compliance with the regulation, as they order products directly from the product manufacturer. In the example used above, this party would be the Toyota Motor Sales, which orders vehicles from the manufacturer in Japan. The Initial Statement of Reasons (ISOR), describing “importer,” however, appears to take the *opposite* approach to common sense and states that “‘Importer’ does not include the distributor that purchases products from the manufacturer and resells them to retailers or to customers.”¹⁰

As described above, the Clarity requirement of the APA requires that any proposed regulation be drafted in such a manner that affected persons may readily understand the proposal. As currently drafted, the proposed regulation fails to meet this standard, as no guidance is provided as to the extent that a person must be involved in arranging for a product to be brought into the United States before they are considered by the Department as conducting “import” activities. The Clarity requirement also provides that an agency description of the regulation must not conflict with the language of the regulation. The ISOR’s statement that distributors are not considered importers directly conflicts with the regulatory language itself.

The Breadth of the “Import” Definition Lacks Necessity – The APA requires that each provision of a proposed regulation be necessary to meet the purposes of the statute, and that the proposing regulatory agency demonstrate, by substantial evidence, the necessity for that specific provision. The regulatory record fails to include substantial evidence demonstrating that retailers and consumers who order products through companies within the United States should be required to comply with the substantive provisions of the Green Chemistry Program. Such evidence does not exist, since only *one* party should bear the responsibility for importing a product—the party who arranges with a *foreign* manufacturer to bring the product into the United States.

¹⁰ ISOR, p. 28, ln. 7-12.

Suggested Fix – Provide language in the definition to clarify that ordering, from a domestic party, a product manufactured or containing components manufactured abroad is not considered “importing.”

(35) “Import” means to bring, or arrange to bring, a consumer product into the United States for purposes of placing the product into the stream of commerce. “Import” includes reimporting a consumer product manufactured or processed, in whole or in part, in the United States. “Import” does not include ordering a product either manufactured outside of the United States, or containing components manufactured outside of the United States, if the order is placed with a person or company located within the United States.

2. “Manufacture” Definition §69501.1(a)(40)

The Proposed Definition of “Manufacture” is Overbroad. The proposed regulation defines “manufacture” generally as “to make, produce, or assemble.” Recognizing that this language is overbroad, the Department appropriately creates exceptions for the following activities:

- “repair or refurbishment of an existing consumer product”;
- “installation of standardized components to an existing consumer product”; and
- “making non-material alterations to an existing consumer product.”

The Department *excludes* from these exceptions any activities that result in “the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product.” Given the very large list of Chemicals of Concern, this exclusion effectively nullifies the exceptions.

New car dealers order vehicles from their franchised manufacturer or distributor, which are delivered to the dealership after being manufactured. On occasion, a vehicle may be delivered with some damage, which the dealership generally repairs prior to sale. Such repairs are made by removing malfunctioning or worn components and replace them with new ones—“assembling” a properly functioning vehicle from a faulty vehicle—activity that appears to fall within the definition of manufacture. For instance, if a vehicle is delivered with defective brake pads, low radiator fluid or an empty tank of gas, the dealer will remedy these problems prior to sale. To bring the vehicle to proper operating condition, the dealer would replace the brake pads, add radiator fluid, and fill the tank with gasoline—in addition to washing the vehicle and buffing out any scratches in the paint. Each of these activities *should be* exempt from the definition of “manufacture,” since this “assembly” activity is the “repair or refurbishment of an existing consumer product,” “installation of standardized components,” and “making non-material alterations to an existing consumer product.” Brake pads, radiator fluid, and gasoline each contain chemicals of concern, however, nullifying the exemptions. One could conclude

(pursuant to the proposed definition of “manufacturer” in proposed §69501.1(a)(41)), that the dealer would now be considered the manufacturer of the vehicle, and thereafter be held responsible for compliance with the substantive provisions of the regulation. Similarly, a dealer who *upgrades* a new vehicle (e.g., by installing larger wheels and tires) installs standardized components on a consumer product—generally not considered manufacturing. Since tires and wheels often contain chemicals of concern, however, the exclusion eliminates the general exception for such activities, rendering the dealer into the vehicle manufacturer for purposes of the Green Chemistry Regulations.

The Proposed Definition of “Manufacture” Lacks Necessity. As described above, common activities by retailers and consumers could render them vehicle manufacturers under the Green Chemistry Regulation. This is unnecessary, as the actual automaker should be responsible for the vehicle, just as the part manufacturer would be responsible for replacement parts or standardize components installed on the vehicle, and petroleum refineries for the gasoline.

Suggested Fix – Delete exclusions from the existing exceptions.

(40) “Manufacture” means to make, produce, or assemble. “Manufacture” does not include any of the following actions, ~~unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:~~

- (A) Repair or refurbishment of an existing consumer product;
- (B) Installation of standardized components to an existing consumer product; or
- (C) Making non-material alterations to an existing consumer product.

3. “Manufacturer” Definition § 69501.1(a)(41)

The Proposed Definition of “Manufacturer” is Overbroad and Lacks Clarity. “Manufacturer,” is defined in the proposed regulation as “any person who manufactures a product, or *any person that controls the specifications and design of, or use of materials in, a product.*” (Emphasis added). While we believe the language of this definition is intended to apply to situations where a retailer directs a manufacturer on the substances to be used in creating a custom-made consumer product, this language is susceptible to a much broader interpretation. Without further context, this definition could be interpreted to include ordering a product configured based upon manufacturer-specified available options. The Department must establish a clear line of demarcation to clarify when activity crosses the line from merely causing a product to be manufactured, as opposed to manufacturing activity itself.

Applied to the retail new vehicle industry, our dealer members order vehicles from their franchised vehicle manufacturers configured based upon a set number of options made available

by the vehicle manufacturer. If, for instance, a Ford dealer orders a Ford Fusion with a six cylinder engine and leather seats, one could broadly construe the draft language to deem the *dealer* to be a manufacturer, as the dealer is controlling the specifications (engine) and use of materials (leather seats) in the vehicle (product).

While the ISOR¹¹ provides context to the proposed definition by clarifying the Department's intent that such configuration activity is *not* sufficient to render a person a manufacturer, such activity should be expressly excluded from the definition of "manufacturer."

Suggested Fix – Provide language in the draft definition to clarify that configuring a product does not render a person as a manufacturer.

(41) "Manufacturer" means any person who manufactures a product, or any person that controls the manufacturing processes and chemical ingredients or formulation used to produce a product. specifications and design of, or use of materials in, a product. For purposes of this paragraph, control does not include the establishment of quality, performance, or design specifications, such as color, size, or material. "Manufacturer" does not include a person who orders a consumer product configured to include optional components, accessories, or characteristics that are offered to multiple parties.

4. "Responsible Entity Definition 69501.1(a)(54)

The Definition of "Responsible Entity" Lacks Clarity. The definition of "responsible entity," includes product manufacturers, importers, and retailers without distinction. This definition is used throughout the draft regulation to denote which party is responsible for compliance for the substantive provisions of the Green Chemistry program. While proposed section 69501.2 provides clarification as to which parties have primary responsibility for compliance with the regulation, contextual language should be added, consistent with section 69501.2.

Suggested Fix – Include language that describes limited circumstances under which a retailer may be considered a responsible entity, in a manner consistent with the "Duty to Comply" provisions of Section 69501.2:

(54) "Responsible entity" means any of the following:

(A) The manufacturer of a consumer product.

(B) The importer of a consumer product.

(C) The retailer of a consumer product may become a responsible entity for one or more specific duties under this chapter related to such consumer product only if notified by the

¹¹ ISOR, p. 29, ln. 20-25.

Department, pursuant to subdivision (a) of section 69501.2, of the failure of the manufacturer and, if applicable, importer of such consumer product to comply with the duty or duties, and the notification includes all of the information provided in paragraph (4) of subdivision (d) of section 69501.2.

5. Retailer “Offramp” Provision Timeline § 69501.2(c):

Portions of the Retailer “Offramp” Provisions of the Duty to Comply Provision Lacks Necessity. Subdivision (c) of Section 69501.2 provides retailers with an “offramp” that they can use to avoid compliance with the substantive requirements of the regulation: within 90 days of notification of a duty to comply under the regulation, the retailer can elect to stop ordering a covered product, and file a notice with the Department containing specified information. This much-appreciated provision allows retailers with a way to avoid complicated and expensive regulatory mandates, and will likely result in significant pressure on any manufacturers and importers who have failed to comply with their own regulatory requirements.

Our concern is the second specified alternative event that may relieve a retailer from responsibility under the regulation: that a manufacturer or importer remedies the non-compliance described in the Failure to Comply Notice within 60 days. The disparity between this 60-day manufacturer/importer deadline and the 90-day deadline to submit a “stop order” notification is unproductive and unnecessary: if a manufacturer or importer remedies non-compliance on day 65, the retailer would *not* be relieved of responsibility and would be required to send a stop order notice—despite the fact that any non-compliance has been addressed.

Suggested Fix – Amend proposed §69501.2(c) to unify the deadlines for compliance exemption at 90 days.

(c) Retailer Option.

A retailer of a consumer product for which the Department has provided notice under subsection (a)(1), shall not be held responsible for complying with the requirements specified in the notice if:

(1) The manufacturer or importer complies with the requirement specified in the Department’s notice, or fulfills the requirements of subsection (b), within ~~sixty (60)~~ ninety (90) days after the Department issues the notice; or

* * *

6. Failure to Comply List §69501.2:

The Regulation Should Provide for Importer Notification of Duty to Comply. Subdivision (a) of proposed Section 69501.2 appropriately specifies that a product manufacturer has the primary obligation to comply with substantive regulatory requirements, followed by the

importer, and (if both parties fail to comply and retailers are notified) finally the retailer. While the regulation provides for a mechanism for notification of a retailer's duty to comply with a mandate, the regulation provides no mechanism for notification of a product's importer.

Suggested Fix – Add a provision to proposed §69501.2 to notify importers of their duty to comply with a regulatory requirement if the manufacturer fails to do so.

PRODUCT AVAILABILITY

Retailers make their living by ordering and selling products that consumers want and need, and by repairing and servicing these products to extend their useful life. Crucial to the success of the Green Chemistry Program is ensuring that this environment is not disrupted. If the Green Chemistry Program results in the removal from commerce of products that consumers need (without ensuring that some alternative is readily available), the Green Chemistry Program will be seen as a failure. A likewise result will occur if parts and supplies to service and repair necessary existing consumer products are unavailable. As described below, the regulation must be amended to ensure that the general chain of commerce is not disrupted.

1. “Consumer Product” Definition §69501.1(a)(35)

The definition of “Consumer Product” is one of the most important provisions of the entire proposed regulation, since it defines the scope of products subject to the regulation. While the proposed definition appropriately “carves out” products that ceased being manufactured prior to being named a Priority Product, it does not carve out products necessary to maintain or repair existing consumer products. Consumers who purchase durable goods—such as vehicles or appliances—rightfully expect the product to have a long useful life. This means ensuring that the product can be serviced and repaired to extend this life. Nor does the proposed definition carve out products that have been purchased for resale prior to being named a Priority Product. Retailers who purchase products for resale that have not been declared Priority Products expect that the products will be perfectly suitable for sale.

As described below, we believe that the current narrowly-prescribed exemptions from the definition of Consumer Product create problems for retailers and our customers. A better approach would be to ensure that consumers and retailers who purchased products prior to being listed as Priority Products should not face negative consequences for their choices—after all, until being listed as a Priority Product, they would not otherwise be put on notice of product concerns.

Regulating Replacement Parts for Historic Products is Contrary to the Forward-Looking Approach of the Green Chemistry Regulation. Throughout the regulation and ISOR, the

Department describes the “forward-looking” nature of the Green Chemistry Program. For instance, the ISOR’s description of the definition of historic product¹² states “[t]his regulation is forward looking and its goal is to accelerate the quest for safer consumer products.” To achieve the goal of seeking to address the development of safer consumer products in the future, the Department should encourage manufacturers to spend their resources on future products. A “Historic Product,” which is appropriately exempt from the Green Chemistry Regulation, is defined as “a product that ceased to be manufactured prior to the date the product is listed as a Priority Product.” This definition fails to exclude parts and supplies necessary to service and repair historic products. When a manufacturer designs and manufactures a product, they do not manufacture all of the anticipated necessary replacement parts for the product—doing so would result in enormous upfront manufacturing and warehousing costs. Instead, based upon the original design, replacement parts are produced on an as-needed basis. Accordingly, a previously-manufactured product that is no longer manufactured when listed as a Priority Product will be exempt from any regulatory oversight, but the parts needed to repair or service the product would not. If a replacement part is named a Priority Product, the manufacturer would be forced to spend significant resources on a product it no longer produces (e.g., in order to comply with warranty obligations, as discussed below in further detail), instead of spending such resources on its current line of products or future products it intends to develop. This approach is contrary to the spirit of the Green Chemistry Program, and creates several policy and procedural concerns as further discussed below

The Proposed Definition of “Historic Product” Creates an Inconsistency with Existing Consumer Warranty Law. California’s Song-Beverly Consumer Warranty Act¹³ (Song-Beverly) establishes specific substantive and procedural requirements that must be adhered to when offering a written warranty for a new consumer product. Included in this crucial consumer protection statute are manufacturer requirements to maintain and establish sufficient service and repair facilities in California to carry out the terms of any consumer warranty,¹⁴ and to “[m]ake available to authorized service and repair facilities sufficient service literature and replacement parts to effect repairs during the express warranty period.” Specific to certain electronic goods and appliances, manufacturers must make such parts available for three or seven years after the product was manufactured—even if this period is longer than the applicable warranty period.¹⁵ If the manufacturer fails to adhere to warranty requirements, the consumer may seek redress against the selling *retailer*, who must either 1) repair the product, 2) direct the buyer to a service facility that *will* repair the product, 3) replace the product, or 4) refund the purchase price.¹⁶ If replacement parts are not available to repair the product, the retailer would be forced to either

¹² ISOR p. 23, ln 28-33.

¹³ Civil Code Sections 1790, *et seq.*

¹⁴ Civil Code Section 1793.2.

¹⁵ Civil Code Section 1793.03.

¹⁶ Civil Code Section 1793.3.

replace the product or refund the customer—either of which would have a severe economic consequences.

By subjecting replacement parts for historic products to the Green Chemistry Regulation, manufacturers of consumer products may face significant cost increases in order to satisfy warranty obligations for previously-manufactured products. After going through the Alternatives Analysis process, these replacement parts would be subject to a regulatory response by the Department, which may include a product sale prohibition (even if an alternative to the replacement part is unavailable).

As an example, consider a new 2012 model year Hyundai Elantra—which is covered by an extensive warranty with terms that vary depending upon the part or system. This vehicle is classified by the California Air Resource’s Board as a “Partially Zero Emission Vehicle” (PZEV)—meaning that the vehicle meets very stringent clean air requirements and is backed by a warranty of 15 years or 150,000 miles on all emissions-related components. Under California law, Hyundai must produce components necessary to satisfy this warranty until 2027. If the Department were to declare one of these components (e.g., a component in the catalytic converter) a priority product, Hyundai would be required to undergo an extensive alternatives analysis for the product, and the product itself would be subject to a regulatory response that may result in use limitations or even product sale prohibitions—even if the product is no longer used in the current model year vehicles. If the part were no longer commercially available, Hyundai dealers would be unable to repair vehicles with faulty emissions system, and would in turn face liability under the Song-Beverly law. Failing to include replacement parts in the definition of historic product—thereby excluding such products from the Green Chemistry Regulation—creates a direct conflict between California’s warranty laws (which are necessarily backward-looking) and the Green Chemistry Program (which should be exclusively forward-looking).

Failing to Exempt Replacement Parts for Historic Products Conflicts with the ISOR, Lacks Clarity, and is Unnecessary. As discussed above, a regulatory proposal lacks clarity, in violation of the APA, if “the language of the regulation conflicts with the agency’s description of the effect of the regulation.” The Initial Statement of Reasons for proposed Section 69501.1(a)(40) (defining “manufacture”) states that “existing products, especially durable goods, may need to have replacement parts available for service, repair, and maintenance. By allowing these three exclusions, repair and maintenance of existing products can continue without the involvement of this regulatory program.”¹⁷ The ISOR goes on to provide examples of ink cartridges and flame sensor switches, explaining the need to ensure the availability of replacement parts, recognizing that “non-original parts may result in compatibility issues,” and noting the problems that would be encountered by consumers if replacement parts containing

¹⁷ ISOR, pp. 28-29.

chemicals of concern were subject to regulatory responses—effectively requiring the purchase of a replacement product instead of repair. Elegantly, the ISOR discussion on the topic concludes with the following statement:

The goal of this regulation is forward looking and is intended to accelerate the quest for safer consumer products. These critical components of durable goods would not represent a high volume chemical in commerce.

Despite this statement of intent recognizing the need for reliable replacement parts, the Department's failure to exempt replacement parts for historic products would subject such parts to the regulation and jeopardize the useful life of historic products themselves. As stated in the ISOR, the Department itself acknowledges both that replacement parts are critical components of durable goods, and do not represent a high volume chemical in commerce; accordingly, these products represent a low-risk exception for a high-value product—regulation of replacement parts for historic products is unnecessary.

The Definition of "Historic Product" Should Include Products Ordered by a Retailer Prior to Being Declared Priority Products. Given substantial discounts that may be realized when ordering products in bulk, retailers often order non-perishable products in large quantities. If a product has not been named a Priority Product at the time of being ordered, a retailer will not be aware of potential risks under the Green Chemistry program that may be incurred by ordering that product. As drafted, a regulatory response could apply to such retailers (e.g., requiring product information posting, use restrictions, product sales prohibitions) for products that a retailer would not be aware of or prepared to implement—particularly if the manufacturer ceases to produce the product. As such, the definition of Historic Product should include products ordered prior to being listed as priority products.

Carve-out for Secondhand Products Should be Clarified. Keeping with the forward-looking approach of the Green Chemistry Program, Part (C) of the proposed definition of "Consumer Products" seeks to exempt secondhand goods from treatment under the regulation. As proposed, Part (C) states that "'Consumer product' . . . does not mean a . . . product previously owned" Such language could be misconstrued as merely stating that this is not equivalent to the definition of "consumer product." The Department should clarify this provision by stating that "Consumer product" does not "include" previously owned products.

Suggested Fix – Amend the definition of "Consumer Product" as follows:

(22)(A) "Consumer product" or "Product" means any of the following:

1. A "consumer product" as defined in Health and Safety Code section 25251;
2. A component that meets the definition of a "consumer product" specified in Health and Safety Code section 25251; or

3. A component, or a homogeneous material within a component, that is identified, under section 69503.4(a)(2)(B), as the minimum required focus of an AA.

(B)1. “Consumer product” or “Product” does not mean any historic product.

2. “Historic product” means any of the following:

(i) a product that ceased to be manufactured prior to the date the product is listed as a Priority Product; or

(ii) a product ordered by a retailer prior to the date the product is listed as a Priority Product.

(C) “Consumer product” or “Product” does not ~~mean~~ include a product previously owned or leased by someone other than the manufacturer, importer, distributor, or retailer of the product.

(D) “Consumer product” or “Product” does not include a product that is used as a spare part or component for repair or maintenance of a historic product.

2. Product Prioritization Process §69503.3(d)

Every product that is currently available in the market plays some role in meeting consumer or industrial demand—otherwise they would not exist. Some models of a product play a role in the marketplace due to relative inexpensiveness, others due to superior quality or performance, and still others due to unique characteristics such as being environmentally friendly. We expect that the mere naming of a product on the Priority Product list will have a major chilling effect on willingness of retailers to stock and sell such products. As such, we urge the Department to amend the regulatory proposal to *require* consideration of the availability of reasonable alternative products when determining whether to list a product as a Priority Product. While the Safer Consumer Products Regulations are intended to play a key role in improving product safety, they should not have the effect of removing a necessary *type* of product from the market when no other alternative exists to take its place.

During the Product Prioritization Process, the Department Should Be Required to Consider the Availability of Alternative Products. When a product is named a Priority Product, the sale and use of that product is likely to decrease in a drastic manner, and the product will likely become very difficult to acquire. If a readily available alternative is economically feasible, industry and consumers will merely switch to the alternative product. If no readily available replacement for that product may be used, consumers and commerce in general may suffer unanticipated consequences. For instance, if a brake-cleaning product were named a Priority Product, and no replacement brake cleaner is readily available, both automotive repair shops and the driving public could find themselves in a situation where their brakes could not effectively be cleaned. In such circumstances, the effectiveness of affected customers’ braking systems would be reduced and public safety could be affected.

To prevent such a result, the Department should be required to at least *consider* the availability of alternative products. While the Department may decide to list the product as a

Priority Product despite the lack of available alternatives, the availability of alternatives should be among other important factors considered in making such a determination.

Suggested Fix – Rather than having the discretion to consider the availability of replacement products when considering whether to name a product a Priority Product, the Department should be *required* to do so. Section 69503.3(d) should be amended to read as follows:

* * *

(d) Safer Alternative. The Department ~~may, at its discretion,~~ *shall* consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product.

REGULATORY RESPONSES

Once a Priority Product becomes subject to a regulatory response, the need of retailers to understand and comply with the mandate is crucial. Our comments seek to appropriately allocate the burdens of such compliance, and to ensure that any such order is appropriate, fair, and issued after the Departmental consideration of all appropriate factors.

1. Department Selection of Regulatory Response §69506

Proposed Section 69506 provides the guiding principles the Department will use in deciding which Regulatory Responses to implement. The proposed language requires the Department to give preference to responses providing for the redesign of a specified product or process (as opposed to administrative or engineering controls), but provides that consideration of other important listed factors (including effectiveness, the capacity of responsible entities to comply, and cost-effectiveness) is merely optional. When determining the appropriate regulatory response to implement, the Department should be *required* to consider each of the important principles described in the subdivision. Requiring consideration of various principles does not impose a mandate that the Department select one response over another, but will ensure that the Department's choice was made after careful consideration of each key principle.

Suggested Fix – Provide that the Department must consider all listed principles by making the following amendments:

§ 69506. Regulatory Response Selection Principles.

(a) The Department shall identify and require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of

alternatives of least concern, where such alternatives are technically and economically feasible.

(b) In selecting regulatory responses, the Department shall give preference to regulatory responses providing the greatest level of inherent protection. For these purposes, “inherent protection” refers to avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process, rather than through administrative or engineering controls designed to limit exposure to, or the release of, a Chemical of Concern in a product.

(c) In selecting regulatory responses, the Department ~~may~~ shall consider ~~any or~~ all of the following factors:

(1) The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product;

(2) The relative cost-effectiveness of the regulatory response as compared to other possible responses;

(3) The administrative and other burdens that would be placed upon the Department, the responsible entities, the product end-users, and the public;

(4) Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations; and~~or~~

(5) The ease and efficacy of enforcement of the regulatory response.

2. Product Information Posting §69506.4

Section 69506.4 of the draft regulation provides procedures by which the Department may, as part of its regulatory response program, order product information disclosures concerning a Priority Product or Selected Alternative to a Priority Product.

Manufacturers and Importers Should Not Be Permitted to Mandate Point of Sale Disclosures Unless Required By Law. The current proposed language provides manufacturers with the option to provide disclosures either by on the product packaging or on an accessible manual, or to shift the product disclosure burden to retailers by requiring the posting of signs at the point of retail display. Retailers are not provided the opportunity to comment on any product information posting requirement proposed by Manufacturers. Manufacturers have every interest to shift the burden of posting information upon retailers at the point of retail display, including cost-reduction and shifting liability for non-compliance away from the manufacturer. In addition to inappropriate allocation of responsibility to a third party, this presents practical difficulties as well.

Given that multiple brands generally exist for each product, the proposed language could result in a major imposition upon retailers who generally display competing brands together. For

example, if a type of shampoo is listed as a priority product to which a regulatory response applies, and seven competing brands all decide to require retailers to post point-of-retail displays, the entire row of a supermarket may be filled with a “waterfall” of similar disclosures—effectively ensuring that *none* of the disclosures are read. To ensure that the disclosures are appropriately made, the regulation should be amended to *require* that the disclosure be provided on the product’s packaging or on an attached manual, and provide a point-of-retail display option only if an applicable law does not allow otherwise.

Suggested Fix – To appropriately place the product information disclosure requirement on the entity familiar with the product, Section 69506.4(b) should be amended as follows:

(b) The responsible entity shall satisfy subsection (a) by making the required information available to consumers, in easily seen, legible, and understandable formats, by both:

(1) Posting the information in a prominent place on the manufacturer’s website and the importer’s website; and

(2) ~~Using one or both of the following means of informing consumers at the point of sale of the information specified in subsection (a):~~

~~(A) Providing the required information on the product packaging or in accompanying written material that is accessible without breaking the product seal, and/or~~

~~(B) If applicable law prohibits providing the required information on both the product packaging and in accompanying written material that is accessible without breaking the product seal, the responsible entity shall post~~ Posting the information in a prominent place at the point of retail display. For products offered for sale online, the point of retail display is/are the web page(s) on which the product is offered for sale.

3. Product Sales Prohibition §69506.6:

The ultimate and most serious regulatory response the Department can select is to prohibit the sale of a Priority Product. Given the graveness of this regulatory response, the Department should only be permitted to do so after significant deliberation and satisfying a high standard of due process. The proposed language provides that a Priority Product may be banned when the Department determines that a safer alternative exists (without a Chemical of Concern) that is both functionally acceptable and technically and economically feasible. Does the Department have the necessary expertise to make these determinations? If the Department is wrong, the consequences to manufacturers, importers, retailers, the consuming public, and California’s economy will be severe. Which parties at DTSC will be making such determinations?

The proposed language goes further to provide that the Department may ban Priority Products even if determining that no safer alternative exists, unless the responsible entity submits documentation (within 60 days of request) demonstrating to the Department’s satisfaction that the public health and environmental benefits of the product outweigh any negative consequences.

As discussed below, this approach is inappropriate.

The Department Should Not Be Permitted to Ban Products When No Safer Alternative Exists. The proposed language provides that a product may be banned despite the fact that the Department determines that no safer alternative exists. Doing so removes an entire *type* of product from the chain of commerce without an alternative and will have a severe impact upon California's economy. This is the exact *opposite* of a forward-looking approach, as it reduces the chain of commerce to a status before that type of product existed. Furthermore, such an extreme approach is entirely unnecessary given that the proposed regulation provides Department with several other regulatory response measures available (i.e., product use restrictions) that can be utilized to minimize harmful public exposure. The proposed regulation should be amended to eliminate product sale prohibitions unless a safer alternative exists.

If the Department Is Permitted to Ban Products When No Safer Alternative Exists, the Factors Considered in Doing So Must be Appropriately Balanced. The proposed language provides that after the Department seeks to ban a product without a safer alternative, the responsible entity has the burden of producing documentation demonstrating that beneficial public health and environmental impacts of the product outweigh adverse impacts. When these are the only factors considered, few, if any, products will pass the test. If, as an extreme example, the Department sought to ban gasoline, refineries would be unable to demonstrate that positive health and environmental impacts of gasoline outweigh negative impacts—they do not. Of course, the public utility and economic benefits of gasoline are the proper factors to be considered. Accordingly, public utility and economic benefits are a more-appropriate set of factors that should be considered.

The proposed language also provides that, should the responsible entity fail to provide *any* documentation within 60 days, the Department may prohibit the sale of the product without further consideration. Given the severe effect of banning an entire type of product where no alternative exists, the standards placed on the Department should be much higher. First, the Department should request documentation from *all* known manufacturers, importers, and retailers of the product—each such party has a stake in a potential product ban. Second, the Department should be required to consider all available information even if no party submits documentation by the 60-day deadline.

Suggested Fix –

Option 1 – Eliminate the ability of the Department to ban products when no safer alternative exists.

§ 69506.6. Product Sales Prohibition.

(a) This section does not apply to a product that does not contain any Chemical of Concern above the applicable alternatives analysis threshold.

(b) Except as provided in section 69506.3 and subsection (e), the requirements of subsection (c) apply to a selected alternative that contains one or more Chemical(s) of Concern, or a Priority Product for which an alternative is not selected, if the Department determines and notifies the responsible entity, under section 69506.1, that there is a safer alternative that does not contain a Chemical of Concern and that is both functionally acceptable and technically and economically feasible. In making such a determination, the Department shall consider the exposure pathways that have the ability to contribute to or cause adverse public health and/or environmental impacts.

(c) Any responsible entity that is the subject of a notification issued under subsection (b) shall cease to place the noticed product into the stream of commerce in California within one (1) year after the Department issues the notification, unless the notification specifies a shorter period of time.

~~(d)(1) Except as provided in section 69506.3 and subsection (e), the Department may issue a notification, under section 69506.1, of its determination that a product containing a Chemical of Concern may no longer be placed into the stream of commerce in California, notwithstanding that there are no currently identified safer alternatives that are both functionally acceptable and technically and economically feasible.~~

~~(2) Prior to issuing a notification under paragraph (1), the Department shall request the responsible entity to provide, within sixty (60) days, documentation that demonstrates to the Department's satisfaction both of the following:~~

~~(A) The overall beneficial public health and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and~~

~~(B) Administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.~~

~~(3) The Department may issue a notification under paragraph (1) if the responsible entity does not provide the requested documentation with sixty (60) days, or if the submitted documentation does not make the required demonstrations to the Department's satisfaction.~~

~~(4) Any responsible entity that is the subject of a notification issued by the Department under paragraph (1) shall cease to place the noticed product into the stream of commerce in California within one (1) year after the Department issues the notification, unless the notification specifies a shorter period of time.~~

* * *

Option 2 – Properly allocate the burden of a product sales prohibition and appropriate weigh public utility against environmental and public health effects.

§ 69506.6. Product Sales Prohibition.

(a) This section does not apply to a product that does not contain any Chemical of Concern above the applicable alternatives analysis threshold.

(b) Except as provided in section 69506.3 and subsection (e), the requirements of subsection (c) apply to a selected alternative that contains one or more Chemical(s) of Concern, or a Priority Product for which an alternative is not selected, if the Department determines and notifies the responsible entity, under section 69506.1, that there is a safer alternative that does not contain a Chemical of Concern and that is both functionally acceptable and technically and economically feasible. In making such a determination, the Department shall consider the exposure pathways that have the ability to contribute to or cause adverse public health and/or environmental impacts.

(c) Any responsible entity that is the subject of a notification issued under subsection (b) shall cease to place the noticed product into the stream of commerce in California within one (1) year after the Department issues the notification, unless the notification specifies a shorter period of time.

(d)(1) Except as provided in section 69506.3 and subsection (e), the Department may issue a notification, under section 69506.1, of its determination that a product containing a Chemical of Concern may no longer be placed into the stream of commerce in California, notwithstanding that there are no currently identified safer alternatives that are both functionally acceptable and technically and economically feasible.

(2) Prior to issuing a notification under paragraph (1), the Department shall request the responsible entity and all known manufacturers, importers and retailers of the product to provide, within sixty (60) days, documentation that demonstrates ~~to the Department's satisfaction~~ both of the following:

(A) The overall ~~beneficial public health and environmental impacts~~ and economic utility of the product ~~significantly outweigh~~ outweighs the overall adverse public health and environmental impacts of the product; and

(B) Administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.

(3) If the Department does not receive the requested documentation within sixty (60) days, the Department shall determine based upon all available information whether the overall public and economic utility of the product outweighs the overall adverse public health and environmental impacts of the product.

(4) The Department may issue a notification under paragraph (1) only if after considering all available information, it determines that the adverse public health and environmental impacts of the product outweigh the public and economic utility of the product. the responsible entity does not provide receive the requested documentation with sixty (60) days, or if the submitted documentation does not make the required demonstrations to the Department's satisfaction.

~~(4)~~ (5) Any responsible entity that is the subject of a notification issued by the Department under paragraph (1) shall cease to place the noticed product into the stream of commerce in California within one (1) year after the Department issues the notification, unless the notification specifies a shorter period of time.

4. End-of-Life Management Requirements §69506.8

Section 69506.8 of the draft regulation provides a requirement under which responsible entities for Priority Products or Selected Alternatives required to be managed as Hazardous Waste in California must implement End-of-Life Management programs.

Imposition of End-of-Life Management Requirements on Non-Manufacturers is Inconsistent with Statutory Authority and Impermissibly Expands the Scope of the Department's Authority. Health & Safety Code Section 25253(b)(7) provides the Department with the authority to impose requirements “for the *manufacturer* to manage the product at the end of its useful life.” (Emphasis added). The proposed regulation imposes requirements on responsible entities, which may also include importers and retailers. Imposing end-of-life management obligations on non-manufacturers is inconsistent with the statutory authority cited by the Department, and would impermissibly expand the scope of authority granted to the Department in violation of the APA and the *Crees* line of cases cited above. Accordingly, the end-of-life management provisions must be narrowly tailored to ensure that any requirements be appropriately borne by manufacturers.

Collection Plans Under Product Stewardship Programs Should Provide for Both Collection Mechanisms and Compensation to Third Parties. While Section 69506.8(a)(2)(B) appropriately requires that collection and recycling plans under a product stewardship program be created in consultation with retailers and potential collection sites, it requires that the plan only contain *either* collection mechanisms *or* compensation to third parties who administer the program. The language should be amended to include *both* collection mechanisms, *and* compensation. Furthermore, the ISOR¹⁸ indicates that the product stewardship program must contain both collection mechanisms and compensation. To satisfy the clarity requirement of the APA (which requires that the language of the regulation be consistent with any agency description of the regulatory effect), the proposed language should be amended as described below.

Suggested Fix – Section 69506.8 should be amended as follows:

§ 69506.8. End-of-Life Management Requirements.

(a) Except as provided in section 69506.3, the manufacturer of ~~a responsible entity for~~ a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that the following requirements are met:

¹⁸ ISOR, p. 170, ln. 20-26.

(1) The information required by section 69506.4 shall be provided for the product. Additionally, the product information must state that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.

(2) No later than one (1) year after the Department issues a notice of compliance for the Final AA Report for the product, the ~~responsible entity~~ manufacturer shall fund, establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:

(A) A comprehensive product stewardship plan must be developed and maintained, after being submitted to the Department for approval. The plan must include all of the following:

1. A list of, and contact information for, participating manufacturers, importers, and other participating persons.

2. The scope of products to be covered by the plan.

3. The roles and responsibilities for manufacturers, importers, retailers, consumers, and government throughout the life cycle of the product, and identification of retailers who have agreed to participate in the program.

4. Identification and description of collection systems that will be used.

5. End-of-life management information, that includes the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse multimedia impacts.

6. Anticipated resources needed to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program.

7.a. A financial guarantee provided by the ~~responsible entity~~ manufacturer to insure a sustainable end-of-life management program for the product.

b. "Financial guarantee" means any mechanism, including the mechanisms described in article 8 of chapter 14, to ensure that adequate funding is available to pay for future end-of-life management costs for products placed into the stream of commerce in California unless the mechanism involves a fee imposed upon retailers or point-of-sale fee upon consumers.

8. Program performance goals, which shall be quantitative to the extent feasible, for:

a. Increasing the capture rate of covered products at the end-of-life; and

b. Increasing recyclability.

9. A description of how each program goal will be achieved.

10. Public education, outreach, and communications plans.

11. A description of public and stakeholder consultation activities during preparation, and in periodic review and updating, of the plan.

12. Reporting and evaluation procedures.

(B) The product stewardship program and plan for collecting and, if applicable, recycling the product must be voluntary for third parties, and shall be developed in consultation with California retailers and owners/operators of prospective collection sites. The collection program must include one or both of the following:

1. Collection mechanisms; and ~~or~~

2. Compensation to retailers and other persons who agree to administer or participate in the collection program.

(C) The ~~responsible entity~~ manufacturer shall provide its product stewardship plan to the Department for review and approval, post a copy of the product stewardship plan on its own website, and provide a link to the posting to the Department for posting on the Department's website.

(D) The ~~responsible entity for~~ manufacturer of a product subject to the requirements of this section shall ensure that a report is provided to the Department annually from the date the end-of-life management program is required to be implemented. The report must include, by total tonnage:

1. The quantity of products placed into the stream of commerce in California over the previous one-year period; and
2. The quantity of products recovered over the same one-year period.

(b) Multiple responsible entities may form a third-party product stewardship organization, funded by participating manufacturers ~~and other responsible entities~~, to provide local services to collect, recycle, or otherwise appropriately manage covered products at the end-of-life.

~~(c) A responsible entity subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A responsible entity may not substitute an alternative end-of-life management program for the program specified in this section unless it receives advanced written approval from the Department.~~

~~(d) A responsible entity manufacturer subject to the requirements of this section may request an exemption from the requirement to provide an end-of-life management program by demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product.~~

5. Regulatory Response Flexibility §69506.10

After establishing a series of procedures that must be completed and considerations that must be given prior to implementing a regulatory response, the proposed language seeks to allow the Department to avoid all such requirements in proposed Section 69506.10. This section provides that the "Department may impose one or more regulatory responses specified in section 69506.2 and sections 69506.4 through 69506.9 to situations other than those specified in those sections." The section also allows periodic (and potentially unlimited) re-evaluation of regulatory responses that may lead to requiring responsible entities to undergo new alternatives analyses. This "flexibility" is inappropriate, as the regulated industry would be subjected to unfettered and unpredictable authority. This proposed section should be deleted.

DUE PROCESS CONCERNS

In addition to the concerns discussed above, one common issue permeates the regulatory scheme: the incredible amount of discretion the Department is provided with which to make decisions of enormous importance to the chain of commerce and consuming public. The

proposed language does not provide sufficient guidance of how information will be reviewed and considered in making determinations—merely providing various opportunities and requirements to submit information and comments to the Department. Will the Department weigh such information equally? Will the Department review and respond to each comment raised? Does the Department intend to comply with APA procedures for each activity that resembles rulemaking? These key questions must be addressed by amendments to the regulation, which be made in consultation with interested entities.

The Proposed Regulation Lacks Clarity Concerning Interaction between the Department and OAL for APA Compliance. The proposed language is unclear how the Department’s decision-making will interact with the APA, and how regulatory responses will be submitted to and reviewed by the Office of Administrative Law. As discussed above, none of the sections cited as authority for the regulatory proposal expressly exempt the Department from the requirement to comply with the APA. Accordingly, all future activity pursuant the Green Chemistry Regulation that would qualify as “rulemaking” activity must comply with the APA. The manner in which deadlines established pursuant to the Green Chemistry Regulations (e.g., due dates related to a regulatory response) will work with the APA’s lengthy proceedings is unclear and must be addressed in the proposed language.

Dispute Resolution Process Is Unclear; Unnecessarily Limited. Pursuant to Article 7 of the proposed regulation, “any responsible entity” may dispute a Departmental decision by following specified procedures, but that the entity waives its right to further contest the disputed issue administratively if it strays from the procedural path outlined in the article. The ISOR goes a step further, clarifying that failure to follow specified procedures results in the waiver of both administrative *and* judicial dispute resolution rights, since the entity would have (apparently conclusively) failed to exhaust administrative remedies.¹⁹ Not only does the ISOR’s description of the regulation’s effect differ from the regulatory language itself, it conflicts with long-established California law regarding the exhaustion of administrative remedies.²⁰

For disputes concerning decisions other than regulatory responses, the proposed language requires an entity to undergo an “informal” dispute resolution process through the Department—and that the dispute must be filed within 30 days “following the notice or website posting of the Department’s decision that is the basis of the dispute.”²¹ If the process does not yield satisfactory results, the entity may appeal that result to the Director within 30 days, submitting “information stating the basis for seeking further review, and the reasons why the decision does

¹⁹ ISOR, p.

²⁰ See, e.g., *Payne v. Anaheim Memorial Medical Center* (2005) 130 Cal.App.4th 729, at 743 “The rule that a party must exhaust his administrative remedies prior to seeking relief in the courts ‘has no application in a situation where an administrative remedy is unavailable or inadequate.’”

²¹ Proposed Health and Safety Code Section 69507.1(a).

not comport with the requirements of this chapter or is otherwise unreasonable.”²² These 30-day deadlines are unreasonably short—particularly for retailers and other parties not actively involved in complying with the substantive provisions of the regulation. The Department has not provided any information demonstrating the factual need to provide such strict deadlines.

For disputes involving regulatory responses, the problem is even worse—a request for review must be filed within 30 days of receiving a determination from the Department. This request must contain “a statement of the reasons supporting the Request for Review, and . . . a showing that the determination is based on . . . (a) Erroneous facts, assumptions, approaches, or conclusions of law; and/or (b) A policy judgment that the Department should, in its discretion, consider.” Given the information that must be submitted along with the Request for Review, no responsible entity could possibly comply with this 30-day timeframe—particularly retailers and other entities not actively involved in the regulatory response process. Furthermore, an entity filing a Request for Review will not be privy to the facts, assumptions, and approaches made by the Department.

Suggested Fix – Article 7 should be deleted, and the Department should create a working group of interested parties to develop a reasonable and appropriate replacement policy.

CONCLUSION

Thank you for this opportunity to comment on the proposed regulation. We look forward to working with DTSC to address our concerns in the near future. If you have any questions or comments concerning this letter or Green Chemistry issues in general, please feel free to contact me at (916) 441-2599, or at jmorrison@cncda.org.

Sincerely,



Jonathan Morrison
Director of Legal & Regulatory Affairs

²² Proposed Health and Safety Code Section 69507.2.

October 5, 2012

DTSC
Office of Legislation and Regulatory Policy
P. O. Box 806
Sacramento, CA 95812-0806
Submitted via e-mail to: gcregs@dtsc.ca.gov

RE: CPSC Comments on Draft Regulations for Safer Consumer Product Alternatives

Dear Director Raphael:

The California Product Stewardship Council (CPSC) is an organization of local governments and businesses from all parts of California who have come together to support a transition to producer responsibility for managing discarded products. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. We support the development of regulations that would promote the re-design of these problem products.

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,



California Product Stewardship Council



October 11, 2012

Ms. Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Via email to: gcregs@dtsc.ca.gov
Via fax to: (916) 324-1808

RE: Title 22, California Code of Regulations. **Safer Consumer Product Alternatives**
Proposed Regulations, R-2011-02: **Comments on July 2012 Text of Proposed Regulations**

Dear Ms. Von Burg:

The California Retailers Association submits the following comments relative to the July 2012 Text of Proposed Regulations.

The California Retailers Association is the only statewide trade association representing all segments of the retail industry including general merchandise, department stores, apparel, mass merchandisers, convenience stores, supermarkets and grocery stores, chain drug, and “specialty” retail such as auto, vision, jewelry, hardware, furniture, home goods, and home improvement stores. California’s retail industry currently operates over 164,200 stores with sales in excess of \$571 billion annually. And our industry employs 2,776,000+ people—nearly one fifth of California’s total employment.

We want to acknowledge the Department for its response to our comments on the previous draft regulation. Of the twelve recommendations CRA submitted to DTSC, five were accepted by the Department, relative to overall retailer responsibility in the Duty to Comply section, timeframe for the retailer off-ramp, elimination of product priority notifications by retailers, and removal of recall provisions. New changes in the July 2012 draft which we *support* include: 1) that there will be no more than 5 products on the first Priority Products list; the ability to petition for de-listing of a COC; and a Priority Products Workplan by 1/2014 that identifies the product categories to be evaluated for inclusion on the Priority Products list during the next three years, thus giving industry a chance to plan ahead accordingly.

There remain sections in the regulation where we urge changes be made to ensure clarity, for compliance's sake. Of critical importance is the definition of "manufacturer". We also have remaining concerns with portions of the Regulatory Response section, and some open-ended areas where we believe the Department has unnecessarily provided itself unlimited discretion. Our comments are organized by section, and in each case we have provided the Department with suggested language that accomplishes the goal of our commentary. We remain committed to working with the Department to develop a workable regulation.

1. Section 69501.1(a)(41): Definition of "Manufacturer"

"Manufacturer is defined as "any person who manufactures a product, or any person that controls the specifications and design of or use of materials in, a product." *The definition fails the clarity standard of the Administrative Procedures Act ("APA").* The phrases "controls the specifications" and controls the "design of or use of materials in a products" are sufficiently unclear to be able to determine precisely which entities will be deemed manufacturers.

Prior to the October 11, 2011 draft, the definition of manufacturer read: "Manufacturer means any person who manufactures a product". The explanation for the change in the definition to that currently proposed is provided by the Department in the Initial Statement of Reasons (ISOR): "The private label retailer may wish to have more control over production and may dictate to the manufacturer specifications for raw material, ingredients or designs in a contract".

We concur with the Department that a retailer that dictates *use of a specific chemical* could be determined to be a manufacturer. However, retailers, as part of the normal course of business, instruct their private label manufacturers as to the general *design* parameters of their order—color, fit, style, or embellishments. Other examples of "design" specifications include: fabric type, cut of garment, cuffs, collars, buttons, grommets, studs, beading, color of garment, thread color, scent, and size. In none of these instances does the retailer know if there is a Chemical of Concern ("COC") in these design determinations. The retailer is *not* manufacturing the product, but providing general directions as what the end product should look like. *Designating design specifications is the retailer's role as the "customer" of the manufacturer. Determining the chemical process or specific chemicals used to produce the desired product is the responsibility and function of the manufacturer.*

As an example, an apparel retailer may direct a manufacturer to make jeans in denim fabric, with a dark wash, with orange stitching on the pockets, in a boot cut style. Has the retailer, who has no knowledge or control of the chemicals contained in the fabric or the thread, become a "manufacturer" because the retailer has "controlled the design" of the jeans?

Has a retailer that orders men's wrinkle-resistant khakis, with pleats and no cuffs become a "manufacturer" because the wrinkle-resistant "spec" means a certain chemical or chemical process must be utilized, even though the retailer has no knowledge of those chemicals or processes about to be used?

Has a general merchandise retailer who asks a manufacturer to make a private label kitchen counter cleaning spray in a 16 ounce spray bottle with a lemon scent "controlled the specification" of the product? The retailer has no knowledge or control of the chemicals used in the packaging, the spray or the scent.

Has a chain drug store that asks a manufacturer to make a private label hand cream in a tube with a lavender scent "controlled the design" of the product? The retailer has no knowledge or control of the chemicals used in the packaging or product.

Even by providing the manufacturer with a private label brand logo to go on the product itself, has the retailer controlled the specs or design of the product such that the retailer is now deemed the manufacturer of the product?

In all of these examples, the retailer has provided the manufacturer with some general specifications and design information, but *does not have knowledge of, nor control of, the materials, chemicals and/or chemical processes used to meet those general specifications*. The actual manufacturer still has the ultimate responsibility for the chemical composition decisions for the product's manufacture.

Without correction, this definition fails the clarity requirement of the APA, since the retailer is subjected to requirements of a manufacturer in a manner that is inconsistent with the Duty to Comply Section 69501.2(a)(1): "A retailer is required to comply with the requirements applicable to a responsible entity ONLY (emphasis added) if the manufacturer and the importer have failed to comply and the Department notifies the retailer of such non-compliance by posting the information on the Failure to Comply List, under Subsection (d)(4)(c)". *Without clarification, the regulation as written will de facto turn thousands of retailers into "manufacturers" under the regulation, which is contrary to the intent of the statute, as well as to the Department's own framework of responsibility under the regulation, as delineated in the Duty to Comply section.*

Proposed Change:

Option 1: Return to the definition of manufacturer included in prior versions of the draft regulation: "*Manufacturer means any person that manufactures a product*". Without the second half of the definition, there are no clarity issues and the definition no longer would conflict with the responsibilities of manufacturers and retailers in the Duty to Comply section.

Option 2: Amend the definition to read: "*Manufacturer means any person that manufactures a product, or any person that controls the manufacturing processes and chemical ingredients or formulation used to produce the finished product. The use of quality, performance or design specifications, such as color, size or material, does not constitute control.*"

2. Section 69501 (b)(1): Purpose and Applicability

It is not clear in the draft regulation whether businesses would have responsibilities for chemical products used internally in conducting business, when those products are *not themselves made available to the public*. One example would be the use of various solvents and adhesives as well as the solder used in the repair of electronic equipment used to support a retail business, but *not* directly sold to consumers. Another example would be wiring or cable used for electronic transmission in the conduct of a retail business, where that wiring and/or cable is *not* sold directly to consumers. We assume that Section 69501 (b)(1) (“...this chapter applies to all consumer products placed in the stream of commerce in California”) means the regulations would not apply to chemical products or processes used internally within a business, because these “products” are not placed into the stream of commerce in California; we request confirmation of this assumption.

3. Section 69501.1(a)(22)(A) and (B): Definitions of “Consumer Product”, “Product” and “Historic Product”

The definition of “consumer product” is one of the most important provisions of the proposed regulation, since it defines the scope of products subject to the regulation. While the proposed definition appropriately “carves out” products that ceased being manufactured prior to being named a Priority Product, it does not carve out products necessary to maintain or repair existing consumer products. Consumers who purchase durable goods such as appliances rightfully expect the product to have a long useful life. This means ensuring that the product can be serviced and repaired to extend this life.

A “historic product,” which is appropriately exempt from the regulation, is defined as “a product that ceased to be manufactured prior to the date the product is listed as a Priority Product.” *The definition fails to exclude replacement parts and supplies necessary to service and repair historic products.* When a manufacturer produces a product, they do not manufacture all of the anticipated necessary replacement parts for the product—doing so would result in enormous upfront manufacturing and warehousing costs. Instead, replacement parts are produced on an as-needed basis. Accordingly, a previously-manufactured product that is no longer manufactured when listed as a Priority Product will be exempt from any regulatory oversight, but the parts needed to repair or service the product would not. This is inconsistent.

The state’s Song-Beverly Consumer Warranty Act (Civil Code Sections 1790 et seq) establishes specific requirements that must be adhered to when offering a warranty or service contract for a new consumer product. This law is enforced by the California Bureau of Electronic Appliance Repair, within the Department of Consumer Affairs. For specified electronic goods, manufacturers must make replacement parts available for three to seven years after the product was manufactured, even if this period is longer than the applicable warranty period. If the manufacturer fails to adhere to the warranty requirements, the consumer may seek redress against the selling *retailer*, who must either repair the product; direct the buyer to a service facility that will repair the product; replace the product; or refund the purchase price. Without the availability of replacement parts for repairs, the alternatives are costly.

Failure to exempt replacement parts for historic products conflicts with the ISOR. The ISOR states that “existing products, especially durable goods, may need to have replacement parts available for service, repair, and maintenance. By allowing these three exclusions, repair and maintenance of existing products can continue without the involvement of this regulatory program.” The ISOR goes on to provide examples of ink cartridges and flame sensor switches, explaining the need to ensure the availability of replacement parts, recognizing that “non-original parts may result in compatibility issues,” and noting the problems that would be encountered by consumers if replacement parts containing chemicals of concern were subject to regulatory responses—effectively requiring the purchase of a replacement product instead of repair. *Despite this statement of intent recognizing the need for reliable replacement parts, the Department’s failure to exempt replacement parts for historic products would subject such parts to the regulation and jeopardize the useful life of historic products themselves.* The Department acknowledges in the ISOR that replacement parts are critical components of durable goods, and do not represent a high volume chemical in commerce. Since these products represent a low-risk exception for a high-value product, regulation of replacement parts for historic products is unnecessary.

Proposed Change:

Add: “‘Consumer Product’ or ‘Product’ does not include a product that is used as a spare part or component for repair or maintenance of a historic product.”

4. Section 69501.1(a)(54): Definition of “Responsible Entity”:

The definition of “responsible entity” lacks clarity. The definition of responsible entity includes product manufacturers, importers, and retailers *without distinction*. This definition is used throughout the draft regulation to denote which party is responsible for compliance for the substantive provisions of the Green Chemistry program. While proposed Section 69501.2 (Duty to Comply) does provide subsequent clarification as to which parties have primary responsibility for compliance with the regulation, consistent language should be added to the definition of responsible entity.

Proposed Change:

Include language that describes the limited circumstances under which a retailer may be considered a responsible entity, in a manner consistent with the “Duty to Comply” provisions of Section 69501.2:

(54) “Responsible entity” means any of the following:

(A) The manufacturer of a consumer product.

(B) The importer of a consumer product.

(C) The retailer of a consumer product *may become a responsible entity for one or more specific duties under this chapter related to such consumer product only if notified by the Department, pursuant to subdivision (a) of section 69501.2, of the failure of the manufacturer and, if applicable, importer of such consumer product to comply with the duty or duties, and the notification includes all of the information provided in paragraph (4) of subdivision (d) of section 69501.2.*

5. Section 69501.2(c): Retailer Option

This section provides that retailers are not responsible for complying with the requirements in a Priority Product Replacement Notification if: 1) the retailer issues a Priority Product Cease Ordering Notification no later than 90 days after the Department has notified retailers of a manufacturer's and an importer's failure to comply; or 2) if the manufacturer or importer complies within 60 days after being listed on the Department's Failure to Comply List.

It is possible that a manufacturer could fail to comply within the 60-day window, but then come into compliance sometime thereafter. The potential for confusion or duplication arises because a retailer has a 60-day window and the manufacturer or importer has a 60-day window. If a retailer sees that a manufacturer has not complied as of the 61st day, the retailer can initiate the stop-order of the product, only to find out that the manufacturer complied on the 88th day. Thus the retailer could have made its stop-order determination and only days later have to reverse the determination because the manufacturer came into compliance. To avoid this potentiality, both timeframes should be consistent.

Proposed Change:

Change Section 69501.2(c)(1) to read "The manufacturer or importer complies with the requirement specified in the Department's notice, or fulfills the requirements of subsection (b), within *ninety (90)* days after the Department issues the notice..."

6. Section 69503.3 (d): Process to Evaluate Products

This section provides that "The Department may, at its discretion, consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product."

The Department should be *required* to consider readily available safer alternatives, rather than allowing it the discretion to do so.

Proposed Change:

Change "may" to "shall".

7. Section 69506 (c): Regulatory Response: Selection Principles

This section states "In selecting regulatory responses, the Department may consider any or all of the following factors", followed by a list of five factors. To provide clarity to the regulated community as to what criteria the Department will use in selecting which regulatory responses to impose, these five factors should be *required* to be considered by the Department.

Proposed Change:

Change "may consider" to "shall consider".

8. Section 69506.1 (b): Applicability and Determination Process

This section requires the Department to notify all responsible entities of a regulatory response the Department is proposing, and to hold one or more public workshops for comments, as well as a 45-day comment period on the proposed regulatory response. We support this process. However, this public notification and input process ONLY applies to: use restriction, product bans, engineering and administrative controls, R&D grants and reevaluation. *Product Information for Consumers and End of Life Management regulatory response options are EXCLUDED from the notice and public comment requirements.* Sub (b) includes reference to Sections 69506.5, .6, .7, .9 and 10; it excludes Sections 69506.4 and .8. This is an inconsistent application of the Applicability and Determination Process. It is also questionable if the Department has the authority to decide that some regulatory responses will be subject to the public notice requirements and others will not.

Proposed Change:

Amend to include both Product Information and End of Life regulatory responses in (b).

9. Section 69506.4 (b)(2)(A) and (B): Product Information for Consumers

These sections allow a product manufacturer to provide required consumer information either on the product packaging OR “posting the information in a prominent place at the point of retail display.” If the manufacturer picks the retail point of display option, the Department will have adopted an option violating the consistency provisions of the APA by mandating a burden on retail that could be met by manufacturers properly labeling their products, inconsistent with the Duty to Comply section that specifies retailers are required to fulfill responsibilities only when the manufacturer and then the importer have failed to do so (Section 69501.2). This will also result in an unmanageable amount of signage at the store level.

Example: An apparel retailer carries 50 different types of denim jeans: dark wash, light wash, various colors, different pocket designs, zippers, decorative stitching, leg widths, etc. These jeans are made by 10 or more companies. If a COC is used in the dyeing or washing of the denim, each manufacturer could provide a sign for each of its denim products. Thus, at least 10 signs, and probably more like 30-40, would be required to be posted at retail *just for those jeans*. Extrapolate that for all the SKUs in a retail store—all the shirts, pants, tops, sweaters, coats, jackets, and other clothing items in an apparel or general merchandise store. This potential posting of *dozens of signs per priority product SKU and manufacturer* is not authorized expressly nor implicitly in the statute.

Although the Department indicated it *prefers* warning labels to be available “prior to purchase”, we believe warning labels ON consumer products are more valuable to the consumer than a sign, because the consumer is bringing the product home, where the information will more likely be read, than while walking past signage in a store environment. We recommend the Department not require product information signage as a Regulatory Response when the hazard is implicit with use of the product, and safe handling instructions are communicated on the product. CRA recommends that the Department shift

its goal to the provision of information to consumer prior to use. For the rare consumer who will read the warning post-purchase and decide against keeping the product, the item can always be returned to the point of purchase. The majority of consumers will read the use instructions, the optimal point for communication of any warning.

The Department could also consider how the Federal Hazardous Substances Act specifies required warnings and utilize its process. As a last resort, the Department could consider “tiering” the information provision requirements. For example, manufacturers would be required to post the information on their website, provide an 800 number for consumers to access for further information, and provide the specified information on the product packaging or label (such as an accordion label). Only in those instances where manufacturer labeling is legally prohibited could signage be posted in a retail location.

Proposed Change:

Amend (2)(b)(2) to read “Use the following means of informing consumers of the information specified in subsection (a):”. Delete “and/or” in (A). Strike all of (B) and insert: “Where chemical ingredient information on the labels of consumer products is prohibited by federal or state law, signage at retail may suffice for compliance with (A).”

10. Section 69506.5: Use Restrictions on Chemicals of Concern and Consumer Products

This section spells out what use restrictions might be imposed by the Department, but contains no standards as to when, or under what circumstances, these restrictions may be imposed.

Proposed Change:

Reduce the arbitrary discretion left to the Department by enumerating the criteria required for the Department to choose a use restriction regulatory response.

11. Section 69506.6 (c), (d) and (e): Product Sales Prohibitions

Section (c) imposes a timeframe within which responsible entities must cease placing a Priority Product into the stream of commerce when the regulatory response adopted by the Department is a sales ban. The responsible entity has one year after the Department issues the notification, “unless the notification specifies a shorter period of time”. Subsections (d)(4) and (e)(2) also specify timeframes of one year, with the same open-ended ability of the Department to specify a shorter timeframe. There are no qualifications or criteria or circumstances established for when or why the Department may shorten the specified timeframe.

Proposed Change:

Option 1: If shortening of the time frame is needed, there must be criteria established for that necessity. The regulated community must know under what set of circumstances the Department is authorized to shorten the timeframes.

Option 2: Remove the ability of the Department to arbitrarily determine a shorter timeframe.

12. Section 69506.8 (a)(2) and (a)(2)(A)(7)(a): End of Life Management Requirements

Subsection (a)(2) requires that the “responsible entity shall fund, establish and maintain an end-of-life management program for the product.” Subsection (a)(2)(A)(7)(a) requires the responsible entity to provide a “financial guarantee” to ensure a sustainable EOL management program for the product. *The Department does not have the authority to expand the responsibility for an EOL program beyond manufacturers of a Priority Product because the enabling statute clearly states that “manufacturers” have the responsibility for EOL programs. See California Health & Safety Code Section 25253(b)(7): “Imposing requirements for the manufacturer to manage the product at the end of its useful life, including recycling or responsible disposal of the consumer product.”* Such expansion would violate the *Crees* decision that a regulation “may not make a rule or regulation that alters or enlarges the terms of a legislative enactment.”

Proposed Change:

Change “responsible entity” to “manufacturer”, in Section 69506.8 (a)(2), and in (a)(2)(A)(7)(a).

13. Section 69506.8 (a)(2)(A): End of Life Management Requirements

This section requires the development and maintenance of a comprehensive product stewardship program with specified components. One of those components (a)(2)(A)(3) includes the “roles and responsibilities for manufacturers, importers, retailers, consumers and government...and identification of retailers who have agreed to participate in the program”. This language appears to leave open the possibility for a manufacturer to create a plan that imposes responsibilities on retailers without consent. In addition, the ISOR references holding “various parties accountable.” There is no authority to impose responsibilities for EOL programs on any entity other than manufacturers, per the statute. Retailers, importers, and other entities can participate in a stewardship program as voluntary participants and the regulation should so note.

Proposed Change:

The Section relating to End of Life Management Requirements must be amended to conform with the enabling statute, which requires the obligation to be placed solely on manufacturers.

14. Section 69506.8 (a)(2)(B): End of Life Management Requirements

In (B) there is a conflict between the regulatory language and the ISOR, which may just be a drafting error. The language currently reads: “The collection program must include *one or both* of the following in the collection program. 1. Collection mechanisms; *and/or* 2. Compensation to retailers and other persons who agree to administer or participate in the collection program.” The ISOR explains that both a collection mechanism and compensation to persons participating in the program should be provided.

Proposed Change:

Delete “one or” in (B), and delete “/or” in (B)1. With this change, the regulation will be consistent with the intent of the Department, with which we concur, as expressed in the ISOR.

15. Section 69506.8 (a)(2)(C): End of Life Management Requirements

Subsection (a)(2)(C) requires a responsible entity to provide its product stewardship plan to the Department for review and approval. The term “manufacturer” should replace “responsible entity” because *product stewardship is an EOL program, which, under the statute, must be imposed only on manufacturers*. Additionally, no public hearing process is required prior to the Department’s approval of the plan. Because the plan may ultimately involve retailers, consumers and other entities, we recommend that a public workshop and a comment period of a minimum of 45 days be required prior to action by the Department to approve or reject the product stewardship plan.

Proposed Change:

Replace “responsible entity” with “manufacturer”. Add language to require public workshop and comment period prior to the Department’s approval or rejection of a product stewardship plan.

16. Section 69506.8 (D)(2)(c) and (d): End of Life Management Requirements

Proposed Change:

In (D)(2)(c) and (d) change “responsible entity” to “manufacturer” in both locations because the statute requires EOL programs to be conducted by manufacturers only and the Department does not have the authority to change the statute’s meaning.

17. Section 69506.8 (D)(2)(c): End of Life Management Requirements

This section permits a responsible entity to seek the Department’s “approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section.” *However, there are no criteria or delineation of the grounds upon which the Department would make an assessment as to whether the alternative achieves the “same results”*. This again allows the Department unbounded discretion. The concern for the retail industry in this section is that the manufacturing community does not support EOL programs unless they can recover their costs through a point-of-sale fee on consumers. (This statement is based on manufacturer positions on EOL legislative proposals on light bulbs, batteries, mattresses, carpet and paint.) Manufacturers have also previously supported mandatory in-store take-back programs for retailers, to avoid the responsibility for manufacturers to have to pay for EOL programs. Because retailers sell tens of *thousands* of products, a POS fee on individual products is not workable for our industry. In-store take back is also unworkable due to space and liability issues. Because the statute clearly imposes the responsibility for EOL programs solely on manufacturers, it is important that the Department *not* approve alternatives that shift the burden to another segment of the supply chain.

Proposed Change:

Establish criteria under which the Department would consider approving an “alternative” EOL program than that specified in the proposed regulation.

18. Section 69506.10 (a): Regulatory Response Selection and Re-Evaluation

This section permits the Department to impose one or more regulatory responses to “situations other than those specified in those sections”. *What* possible situations does the Department envision? The section is not clear, and overly broad. The Department confers upon itself unlimited discretion to impose any regulatory response it chooses, under any circumstances, which exceeds the authority of the statute.

Proposed Change:

Delete, or narrowly define and clarify what is meant by “situations other than those specified”.

19. Section 69506.12: Regulatory Response Report and Notifications

A manufacturer (or, if applicable, importer) that is subject to a regulatory response must provide a Notice of the impending regulatory response to retailers of the covered product(s). Included in the Notice is the “due date for implementing the regulatory response”. The Department is also required to post on its website a Regulatory Response Summary that includes “the implementation due date”.

It is not clear in the regulation how the due date of a regulatory response will be determined, by whom, and what the timeframe will be for implementation of each of the possible regulatory responses.

If the regulatory response involves a product stewardship program, a sales restriction, a sales ban, or signage, the retail industry will need sufficient notice and time to comply. The absence of established due dates in the regulation leaves open the possibility that manufacturers and the Department could agree on an effective date for a particular regulatory response that is operationally unworkable for the affected retailers. For example, the Notice could arbitrarily announce that the selected regulatory response takes effect in 14 days, or 30 days, or any other timeframe that would be insufficient for compliance.

Proposed Change:

We request that the section be amended accordingly, to provide a minimum time threshold for retailer compliance with the specified regulatory response: “A description of the required regulatory response(s) and the due date for implementing the regulatory response(s), which in no case shall be less than 180 days from the date of the notification.”

Ms. Krysia Von Burg
October 11, 2012
Page twelve

20. Section 69507.1 Informal Dispute Resolution Procedures

The section specifies that if a request for dispute resolution is not received within a certain time period, the Department's decision is "final and not eligible for any dispute resolution procedures under this Article." It is unclear if the Department intends by this statement that the failure to pursue an administrative dispute resolution precludes a responsible entity from seeking judicial review; usually failure to exhaust administrative remedies precludes judicial review.

Proposed Change:

Clarification of relationship of informal dispute resolution with judicial review.

Thank you for your consideration of our comments. If there are questions about any of our concerns and related recommendations, please let us know. And again, we appreciate the enormous amount of effort that Director Rafael, Odette Madriago, Colleen Heck and their staff members have put into the very difficult task of developing the Safer Consumer Products regulation.

Sincerely,

A handwritten signature in cursive script that reads "Pamela B Williams".

Pamela Boyd Williams
Executive Vice President



California Stormwater Quality Association[®]

Dedicated to the Advancement of Stormwater Quality Management, Science and Regulation

October 11, 2012

Debbie Raphael, Director
California Department of Toxic Substances Control
Office of Legislation & Regulatory Policy
Attn: Krysia Von Burg, Regulations Coordinator; gcregs@dtsc.ca.gov
P.O. Box 806
Sacramento, CA 95812-0806

**Subject: Comments on Draft Regulations for Safer Consumer Product Alternatives
(July 2012)**

Dear Ms. Raphael:

The California Stormwater Quality Association (CASQA)¹ appreciates the opportunity to review and comment on the proposed Regulations for Safer Consumer Product Alternatives.

We view the regulations as an essential component of our efforts to comply with the federal Clean Water Act and the State Water Code. Controlling problem chemicals at the original source—in consumer products—is often the most cost-effective and for some pollutants is the *only* effective method of ensuring they do not end up threatening aquatic life and human health. If problem chemicals are addressed in consumer products, then State and local agencies will not be forced to install, maintain, and operate expensive treatment facilities in stormwater systems.

We appreciate the changes that have been made to earlier versions of these regulations, particularly those changes that will allow the program to address degradation and reaction products. The substantial effort by DTSC staff is evident in the increased focus in this latest draft on protecting the environment, especially water quality, and other changes to address our earlier comments.

We strongly support adoption of the regulations and encourage DTSC to move forward with finalization of the rule. Timely implementation is important for California.

To ensure that the regulatory program has the capacity to prioritize the water polluting products that pose the greatest threats to surface water quality—and the greatest challenges to remediate, we recommend two minor modifications to the regulations, which we detail below.

¹ CASQA is comprised of stormwater quality management organizations and individuals, including cities, counties, special districts, industries, and consulting firms throughout California. Our membership provides stormwater quality management services to more than 22 million people in California.

Add Clean Water Act 303(d) list to the Chemicals of Concern list and provide the means to address these water pollution problems in the program's first phase

In Section 69502.2(a), "Chemicals of Concern Identification," only pollutants listed under section 303(c) of the Clean Water Act are included. A different list, developed by the Water Boards every few years under Section 303(d) of the Clean Water Act, lays out the state's priority water pollution problems. While there is significant overlap between pollutants in section 303(c) and pollutants that have resulted in 303(d) impairments, there are some important differences in how these lists are developed. Water bodies may be deemed impaired under section 303(d) for any pollutant, not just those listed under 303(c). Unlike the Section 303(c) list, the Section 303(d) list is updated regularly. The 303(d) list meets all of DTSC's stated criteria for inclusion among the lists of chemicals of concern. Including both 303(c) pollutants and the 303(d) pollutants in the "Chemicals of Concern Identification" will ensure that the highest priority water pollution problems in the state can be addressed. We request that DTSC include 303(d) pollutants in Section 69502.2(a), Chemicals of Concern Identification.

The proposed regulations constrain the initial list of priority products² in a manner that excludes many chemical pollutants commonly associated with water pollution in urban waterways. To address this, we recommend that DTSC modify Section 69503.3(g) to provide the ability to address pollutants on the Clean Water Act 303(d) list, since this is the Water Board's list of California's water pollution problems.

Use economic impacts on cities and counties and state agencies as a basis for prioritizing chemicals and products

The costs to public agencies of removing chemicals from stormwater runoff are very high. These costs include complying with stormwater permit requirements, such as TMDL implementation costs, monitoring costs, stormwater conveyance for treatment as well as the treatment itself, and costs for other alternative waste management practices to prevent water pollution. In particular, building end-of-pipe treatment on storm drain systems is very costly. We have estimated the treatment cost for just one pollutant (copper) would be in the billions of dollars.

It is our assessment that DTSC has the legal authority to consider the potential costs to California municipalities, special districts and other agencies in determining which chemicals to list as chemicals of concern, and in prioritizing these chemicals. These are the costs avoided if the regulations effectively address the pollutants in consumer products.

The Green Chemistry statute, AB 1879, allows DTSC to consider these local government costs. AB 1879 was codified as Health and Safety Code section 25252 through 25255. Section 25252(a) states that DTSC "shall establish an identification and prioritization process that includes, *but is not limited to*, all of the following considerations: (1) The volume of the chemical in commerce in this state. (2) The potential for exposure to the chemical in a consumer product. (3) Potential effects on sensitive subpopulations, including infants and children." [*emphasis added*] This language makes clear that the process of listing and prioritizing is required to include, at a minimum, the three listed considerations. However, it implies that DTSC is expected to include considerations beyond those three. The language of AB 1879

² See page 29 of 78, line 5, subsection (g): "(g) Initial Priority Products List(s). Prior to January 1, 2016..." Chemicals of Concern limitations prior to 1/1/16 require that all chemicals be human pollutants (human-based lists).

CASQA comments on Proposed Regulations for Safer Consumer Products

expressly permits DTSC to consider additional factors in determining which chemicals to list as chemicals of concern, and how to prioritize products containing those chemicals of concern.

In fact, in its draft regulations, DTSC recognizes that it is expected to include additional considerations in listing chemicals of concern, and prioritizing products by including additional considerations not described in the statute. Sections 69502.2(b)(1)(A) and (B) include multiple additional factors DTSC is to consider in identifying chemicals to be included as a Chemical of Concern. For example, section 69502.2(b)(1)(A) requires DTSC to consider “*The ability of the chemical to contribute to or cause adverse public health and/or environmental impacts, considering reliable information relevant to the following factors: ... 6. The chemical’s environmental fate; 7. The human population and/or aquatic, avian, or terrestrial animal or plant organisms that would be adversely impacted ...*” Section 69503.2 of the proposed regulations also includes a lengthy list of factors DTSC must consider in prioritizing a product. DTSC has obviously recognized it may include many considerations beyond those expressly included in the statute.

Finally, the intent of the Green Chemistry statutes is to address the harm of chemicals contained in consumer products prior to those products becoming wastes. Identifying chemicals of concern and prioritizing products involves evaluating the harm of those chemicals and products to people and the environment. The cost to local governments in responding to the physical and biological environmental impacts of chemicals in consumer products in stormwater is an important measure of the harm of that chemical to the environment. Considering these costs in determining which chemicals should be listed as chemicals of concern, and which products to prioritize, is not only contemplated by the language of AB1879, but also furthers the intent of that statute.

To provide for this, we request that DTSC make minor modifications to Sections 69502.2(b) and 69503.2 to include the potential costs to local governments, including those incurred by stormwater programs, as a major factor in determining which chemicals to list as chemicals of concern and which products to prioritize.

We are optimistic that the Green Chemistry Initiative, including these regulations, will constitute a major step forward in protecting the environmental resources of California.

Thank you for the opportunity to provide comments. Please contact Geoff Brosseau, our Executive Director, at (650) 365-8620 if you have any questions or need additional information, or me at (714) 955-0670. We are also available to meet at your convenience to review the issues described in these comments

Very truly yours,



Richard Boon, Chair
California Stormwater Quality Association

cc: Odette Madriago, Chief Deputy Director, DTSC
Charles Hoppin, Chair, State Water Board
Frances Spivy-Weber, Vice Chair, State Water Board
Tam Doduc, Member, State Water Board

CASQA comments on Proposed Regulations for Safer Consumer Products

Steven Moore, Member, State Water Board

Felicia Marcus, Member, State Water Board

Tom Howard, Executive Director, State Water Board

Jonathan Bishop, Chief Deputy Director, State Water Board

Darrin Polhemus, Deputy Director, State Water Board

Vicky Whitney, Deputy Director, State Water Board

Rik Rasmussen, Acting Assistant Deputy Director, State Water Board

Paul Hann, TMDL Section Chief, State Water Board

Bruce Fujimoto, Surface Water/Permitting Section Chief, State Water Board

Nancy Woo, Acting Water Acting Director, Water Division, USEPA Region IX

CASQA Board of Directors and Executive Program Committee



October 8, 2012

Director Debbie Raphael
California Department of Toxic Substances Control
State of California
1001 I Street
Sacramento, CA 95812

RE: Safer Consumer Products Draft Regulation (July 2012)

Dear Director Raphael,

On behalf of the California Travel Association (CalTravel), we write to express our deep concerns regarding the July 2012 Safer Consumer Products draft regulation pursuant to Assembly Bill 1879 (Feuer) and Senate Bill 509 (Simitian) passed in 2008. The travel and tourism community is committed keeping California's residents, visitors and the environment healthy yet we have grave concerns about the current structure and requirements of this proposed regulation and believe that the current draft is unworkable.

As a nonprofit association, CalTravel unifies our state's many travel-related businesses by bringing the travel and tourism industry together to deliver an exceptional California experience. The travel and tourism sectors generate more than \$87.7 billion for the state economy, employ over 881,100 Californians directly and bring in approximately \$1.9 billion in local taxes and \$3.4 billion in state taxes. Our industry represents a broad array of travel and tourism interests including theme and amusement parks to museums, restaurants to wineries, retail to lodging. In order for the Safer Consumer Products program to achieve success without devastating the business community, we need a clear prioritization process limited to consumer products with a reasonable approach to identifying alternatives.

We associate our comments with those provided by the Green Chemistry Alliance and are hopeful the Department will consider revisions to the following components;

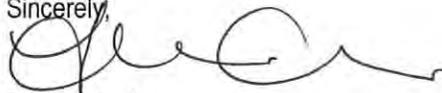
- Unless data has been presented to the contrary, the Department shall not act upon inaccessible components. (Sections 69501.1& 69503.2)

- Unless data has been presented to the contrary, the Department shall not insist on an alternatives analysis for a product of concerns containing a chemical of concern if under a reasonable amount, 0.1% for example. (Section 69503.5)
- Unless data has been presented to the contrary, the Department shall not act upon a product where another federal or California State regulation addresses the same risk of injury or environmental threat. (Section 69501)

When stakeholders agreed to the aforementioned legislation in 2008, we did so based on the assurance that the Safer Consumer Product program would be based on sound-science and would affect the most immediate chemicals and products of concern. Under the proposed regulations however, the Department has given itself incredible authority to act well beyond the original intent. We urge the Department to consider the most effective and least burdensome approach which will yield the results all Californians, our visitors and the environment deserve. A successful program is an achievable program and we're hopeful the Department will seriously consider these concerns and revise the July 2012 proposal accordingly.

CalTravel is committed to ensuring these regulations provide a workable solution and we look forward to working with you on these outstanding issues. Thank you in advance for your consideration.

Sincerely,



Teresa Cooke

Advocate, California Travel Association

CC: Matthew Rodriguez, Secretary, California Environmental Protection Agency
Odette Madriago, Chief Deputy Director, Department of Toxic Substances Control
Krysia Von Burg, Regulations Coordinator, Department of Toxic Substances Control

October 11, 2012

Via US Mail and E-Mail GCRegs@dtsc.ca.gov

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

SUBJECT: Draft Regulations for Safer Consumer Products (July 27, 2012 Release)

Dear Ms. Von Burg:

The California Chamber of Commerce (CalChamber) submits these comments to the Department of Toxic Substances Control (DTSC or Department) regarding its proposed safer consumer products regulations (Proposal or Proposed Regulations) as released on July 27, 2012.

The CalChamber represents the interests of more than 13,000 California businesses. Over 75% of CalChamber members are small businesses, with 100 or fewer employees. Nearly a quarter of all jobs in the private sector in California are provided by our members.

The Department's governing statutes, AB 1879 and SB 509 [codified in 2008 in Article 14 of Chapter 6.5 of the California Health and Safety Code] provide that the Department shall develop regulations which ensure "ease of use and transparency of application," that employ "simplified and accessible tools"¹ and that do not attempt to "supercede the regulatory authority:" of other agencies or "duplicate" or are "conflicting" with other regulatory requirements.² The Proposal fails this basic test.

Moreover, the proposed regulations do not provide adequate information on how large and small businesses will be impacted, how they will be regulated and how their compliance will be judged by the Department.

We believe that many, if not all, CalChamber members will be directly impacted by the Proposed Regulations to the extent that the large list of targeted chemicals are in many product types, which will be imposed with an unclear set of obligations passing through

¹ Health & Safety Code §25253(c)

² Id. §25257.1

the entire product supply chain. Furthermore, because the Department has failed to articulate the specific requirements of these regulations, we cannot advise our members as to what these Proposed Regulations will cost, what to expect and how best to plan for compliance.. But those details are absent in this Proposal or have been deferred to an as yet undeveloped website in the future.

Proposed Regulations are Incomplete: Pathway to Compliance is Unknown

We are very concerned that the Department still hasn't provided specifics on how it is going to implement these Proposed Regulations, and is unable to answer some very basic questions about implementation even though the Department has had over four years to plan its implementation. . For example, the Department cannot specify if the public will have the opportunity to comment on a formal rulemaking of the content of the future website. Moreover, the Proposed Regulations are so incomplete that the Department itself cannot provide any analysis, economic, multimedia or environmental, of what it is proposing. Given that so many issues remain inadequately described or completely unaddressed, and seem to be resolvable only in a subsequent regulatory proceeding, the Department should not proceed until it can put forth a comprehensive regulatory package with all its requisite parts.

It is unacceptable that the Department won't even inform our members as to whether they will have the opportunity to comment in a formal rulemaking on that future web content. Rather, the Department issued a cursory and entirely uninformative response to our letter which merely sought clarification on how the Department intends to implement future steps identified in the Proposal, and whether public review and comment would be permitted once these details were developed (Letters attached as Exhibit A). We cannot understand why the Department refuses to provide a clear response to these concerns.

Basic Unanswered Compliance Questions: Summary

Below we outline some commonly asked questions from our members about how they may be impacted and what they need to do to ensure compliance that the Proposed Regulations currently do not answer.

- What chemicals that I use will be regulated?
- What information, data and studies will be required of me?
- What products that I make, sell or import will be regulated?
- How do I perform an adequate alternatives analysis?
- What criteria will be used to determine what potential regulatory actions apply to me?

These are very basic questions to which any person should be able to discover the answers by reading the Proposed Regulations. Unfortunately, the Proposed Regulations do not answer them. A more detailed discussion of why these are so important is provided below.

Businesses need to be able to objectively determine what their regulatory compliance obligations and associated costs will be and to plan, hire and invest accordingly.

Potential Economic Impacts Are Severe

The Department has totally abrogated its responsibilities to provide policy makers and the public with the potential for adverse economic impact, as specified by the Administrative Procedures Act and the State Administrative Manual. To date the Department has provided little more than a cover letter without any analytic rigor and that merely describes the benefits without any discussion of risks and costs of the regulation. Moreover, the Department has ignored readily available literature and data that quantified the costs of similar initiatives.

We recognize that there are a number of uncertainties involved with estimating the potential for adverse impact on California businesses. However, because the Department has failed to perform even a basic good faith review, tThe California Foundation for Commerce and Education (CFCE is a policy institute affiliated with the California Chamber of Commerce) commissioned a well-regarded policy analysis firm, Andrew Chang & Company, to independently assess the impacts of the Proposed Regulations.

The study found that over the next 25 years the potential net costs to California businesses and consumers could reach \$150 billion and could lead to more than 100,000 direct lost jobs at the peak of implementation. The study leveraged readily available data and literature on Green Chemistry programs and leveraged readily available data and literature on Green Chemistry programs and was based in part on a number of analyses of a similar – though less stringent – regulation recently adopted by the European Union.

The study also found that the timing of costs and benefits realization is critically important to understanding the regulation. Costs are certain and front-loaded while the full benefits from reduced medical spending and increased productivity will not be fully realized until several decades later. Inasmuch, even the descriptive declaration that the Proposed Regulation will lead to positive economic benefits made by the Department is likely flawed.

Other commentators have raised similar concerns. For example, the European Union has recently noted that small or medium sized enterprises “selling only relatively few priority products will never be able to set up the very demanding and costly End-of-Life Management Requirements” described by the proposed regulations.³ Several members of the California Legislature have also expressed their concerns and not received adequate answers from the Department. (Letters from Legislators and DTSC Response attached in Exhibit E.)

³ Comments of the European Union, September 11, 2012 at p. 3

We recognize that the Department's economic analysis is "Preliminary" as stated on the Department's Form 399 submission, and we trust that we will be able to review the Department's completed "Final" analysis prior to the adoption of the regulation.

Basic Unanswered Compliance Questions: Detailed Discussion

The CalChamber has many concerns about the Proposal but in this letter will focus only on the key questions that must be addressed by the Department before it can move forward with the Proposed Regulations.⁴

What chemicals that CalChamber members use will be regulated?

It is incomprehensible why the Department cannot provide the list of chemicals it intends to regulate, particularly since Department representatives have stated in public forums that such a list presently exists.- Not only has the Department not performed the duties required by the statute, it hasn't even bothered to assemble the names of the chemicals where a company could ascertain if it is affected by this Proposal.

The statute requires the Department "*to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.*" Health and Safety Code § 25252(a). It is axiomatic that a chemical would be "of concern" if it poses a risk of harm.

Instead, the Department references a series of lists of chemicals that it may draw from and add to in the future in a process that neither identifies the chemicals, nor prioritizes the chemicals. In public forums, the Department refers to this list of lists as its "flexible palette" giving DTSC unlimited selection discretion, yet not affording the public the benefit of the Department's compliance with the Administrative Procedures Act (APA) so that informed input can be provided on those selections. While it is true that all the chemicals on these lists were reported to have demonstrated some hazard trait in some test that landed them on a particular list for some specified purpose, it does not follow that they all pose a risk of harm if used in a consumer product. A scan of some of the chemical lists referenced in the regulation finds that they include coffee, glass, talc, wood dust, salted fish, bracken fern, and aspirin. We suspect that such chemicals and mixtures are not among those being "prioritized" by the Department, but since these array of lists have merely been referenced but not prioritized, no one can be sure.

⁴ We are not providing exhaustive comment on each and every issue presented by the Proposed Regulation under all laws in this letter. We are incorporating by reference our previous comment letter dated October 30, 2011 (attached as Exhibit B), as well as the exhaustive comments submitted by members of CalChamber, their respective trade associations, and their consultants, including but not limited to TechAmerica, the Alliance of Automobile Manufacturers, the Consumer Specialty Products Association, the American Chemistry Council, the American Cleaning Institute, the California Foundation for Commerce and Education, ICF International, and Sierra Research.

The Department proposes to defer until some unknown future date the hard work required by the statute to identify, to prioritize and to apply scientific criteria to which of the chemicals on these lists may pose a risk of harm and thus should be designated as a “chemical of concern.” This work should not be put off. Rather, before proceeding further with this Proposal, we request the Department to follow the requirements of the Health & Safety Code, and the APA, and identify and prioritize its list of chemicals of concern with the names of the chemicals, and provide a predictable, scientifically-based process to produce and amend that list that can be objectively understood by our members.

What information, data and studies will be required of CalChamber members?

The Proposed Regulations appear to allow the Department near limitless discretion to require regulated parties to submit whatever information the DTSC decides to ask for. However, nothing in either AB 1879 or SB 509 delegated to Department such an unlimited power.

According to the proposed regulations, the criteria the Department will use to determine what information to seek from a member of CalChamber is any “*information it determines is necessary to implement this chapter.*” § 69501.4(a). This will include the submission of “*existing information*” as well as the requirement “*to generate new information.*” § 69501.4. Basically, any information the Department wants it can ask a CalChamber member to provide or generate, and yet no provision of the DTSC’s governing statutes can be cited to support such sweeping authority.

The problem goes beyond breadth, however. It is not clear when a CalChamber member may be required to provide this information or in what time frame, as those decisions will also be deferred into the future and be made subjectively on a case-by-case basis. CalChamber members will be required to submit the requested information or data “*in accordance with a schedule specified by the Department*” and “*within the time period specified by the Department.*” See §§ 69501.4(a)(3) and (4), 69501.4(c)(1).

CalChamber members may not even be aware that this information is being requested of them since the Proposed Regulations do not require notice to affected entities. “*The Department may request that information be made available to it*” by mail, by listserv or by merely posting it on their website. § 69501.4(b)(2). Even though a CalChamber member may not receive actual notice of the request, the member risks being placed on the Department’s Response Status List as non-compliant unless it has “*demonstrated to the Department’s satisfaction that it does not have and is unable to produce the requested information.*” § 69501.4(C)(1)(C).

It is impossible for an objective person to determine the criteria or standard that must be met when submitting information. The Proposal needs to ground any request for data in statutory authority and specify the level at which the Department will be satisfied. Businesses cannot prepare or plan or make appropriate investments when they can be subject to repetitive, arbitrary, and unlimited, information requests from a government

agency. Nor can they even adequately provide comment in this rulemaking on the reasonableness of potential future data requests that are so ill-defined.

The APA demands of all administrative agencies that they give specificity and clarity to their regulations, and that the Department carefully consider the scope and type of information it will need to implement the law and to then specify that in its Proposed Regulations so that stakeholders can understand how they are affected and can provide meaningful comment.

What products will be regulated?

It is not possible to read the Proposed Regulations and determine which products will be regulated. This work too has been deferred to an unknown future date. Yet, the process outlined for eventually selecting priority products is alarming in both its vagueness and its reach. Under the Proposal, it is entirely within the Department's discretion to select a product based on a very broad list of about 30 factors – many of which improperly invade the regulatory jurisdiction of other agencies, and conflict with other well-established regulatory programs. The Proposal states that “[t]he Department may identify and list as a Priority Product, . . . , one or more products it determines to be of high priority.” § 69503.2(a). There is no scientific selection or weighting criteria that can be objectively understood, or that provide any measure of predictive value to potentially affected stakeholders.

After an internal departmental process to consider the factors in the absence of objective criteria, the Department will post a draft work plan of Priority Products. There is no provision for potentially affected stakeholders to obtain notice that their product is possibly included in this work plan. Only those businesses that have signed up for the DTSC listserv or regularly monitor the Department's website will be afforded notice. § 69503.3(f)(4).

If a business does happen to learn that one of its products have been selected in the work plan, it will have only sixty (60) days to determine whether its products contain the chemical of concern in amounts that would trigger further regulatory review.

It is necessary that the details of how the Department intends to identify and prioritize products be readily and objectively understood by reading the Proposed Regulations.

How does a company perform an adequate alternatives analysis?

The statute requires the Department to “*establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.*” Health and Safety Code § 25253(a)(1). In the Proposed Regulations, this process is called the “Alternatives Analysis.”

The statute also requires, in developing the alternatives analysis process, the Department *“shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.”* Health and Safety Code § 25253(c)[emphasis added].

Rather than do the work necessary to develop a clear alternatives analysis template and the tools that would enable CalChamber members to clearly understand what will be required of them, the Department has not included those in this Proposed Regulation but has also deferred these important implementing details to a posting on its website in the future. The Proposed Regulations state:

“Before finalizing the initial list of Priority Products under section 69503.4, the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article. The Department shall periodically revise and update the guidance materials.” § 69505(a).

In addition to not providing the necessary details on how a regulated entity is expected to comply, the Proposed Regulation also lacks criteria on what constitutes compliance and how the alternatives analysis will be judged by the Department. Rather, in its Proposal, the Department gives itself unrestrained authority to determine compliance in any way and at any time it wants.

“Notwithstanding any other provision of this chapter, failure of the Department to make a compliance determination for a Preliminary or Final AA Report within the applicable timeframe specified in section 69505.6, or failure of the Director or the Department to respond to an appeal or Request for Review submitted under article 7 within sixty (60) days, shall not cause a Preliminary or Final AA Report to be deemed compliant with this article.” § 69505.1(i).

Also, it is not clear what will be considered “reliable information” or what will be considered an “adverse impact” and how regulated entities and the Department are to make weighting determinations of the various ingredient and product design choices in the alternatives analysis. The definitions of “reliable information” and “adverse impacts” provided in the Proposed Regulations are quite open-ended. Despite forty years of environmental laws setting thresholds for impact, it appears that any change, even a single molecule, could trigger regulatory requirements, and that the values for the metrics to assess the data can come from any source considered to be an “authoritative organization” which is defined to include non-governmental organizations. § 69505.4(b)(4)(B), citing § 69401.2(b).

There are other glaring deficiencies impacting the AA process. For example, the European Union noted in its objections that although the Proposed Regulations require that both a Preliminary and Final AA Report be conducted by a person (“certified

alternatives assessor”) who is “accredited” by a qualified “accreditation body”, given the demanding criteria for such accreditation, it is entirely uncertain “that there will be enough certified assessors to conduct all AA as of 2016”.⁵ The DTSC’s Proposal in fact is entirely up in the air on this critical component.

The inability of CalChamber members to understand how they are impacted by the Proposed Regulations’ vagaries and overbroad definitions is compounded by the unauthorized bifurcation in the development of regulations to implement the green chemistry statute. The authority to establish regulations is exclusive to the Department. See, e.g., Health and Safety Code §§ 25252, 25252.5, 25253, 25255, 25257.1. OEHHA’s role was merely to provide consultation to the Department on the hazard traits to be included in the online toxics clearinghouse. Health and Safety Code § 25256.1. Despite the lack of statutory authority, OEHHA conducted a rulemaking but at a time when it was not clear or understood how what they were proposing would have any impact on regulated entities. OEHHA’s charge was merely to provide consultation to DTSC on its online toxics clearinghouse, and in fact, OEHHA called its regulations, “*Green Chemistry Hazard Traits for California’s Toxic Information Clearinghouse.*” 22 CFR §§69401-69407.1.⁶ Since the Department had yet to commence its formal rulemaking, regulated entities could not provide meaningful input to OEHHA on ways that DTSC would later make use of its definitional provisions.

Now, in nearly a dozen instances, the Proposed Regulation cites to a section in Chapter 54, which are the regulations that the Office of Environmental Health Hazard Assessment (OEHHA) concluded over a year ago. E.g., §§ 69405.4, 69405.8, 69405.1, 69405.2, 69405.3, 69405.6, 69407.2, 69405.5. Now, for the first time, it is possible to see how the hazard trait definitions that we once thought would only apply to the development of the online toxics clearinghouse, will be used in the broader regulatory program DTSC is designing. Regulated entities, however, are deprived of meaningful comment on both sets of regulations as a result of the unauthorized bifurcation.

With the lack of objective criteria and open-ended definitions of “reliable information” and “adverse impact,” businesses will be subject to the very real potential of a scarcity of “certified assessors,” at risk of paying exorbitant fees for services of the few that obtain such accreditation, and, even then, will not know when they have done an adequate job in performing the alternatives analysis. The standards of adequacy and compliance are subjective. Regulated entities will not know what they are until some point in the future, when at the sole discretion of Department employees they are determined on a case-by-case basis.

“The Department may at any time require a responsible entity to provide, within a time frame specified by the Department, any information supplementary to the

⁵ European Union Comments, September 11, 2012 at p. 5.

⁶ Chapter 54 in its entirety is attached as Exhibit D.

Final AA Report that the Department determines is necessary to select and ensure implementation of one or more regulatory responses that may be imposed under this article.” § 69506.2(a).

“The Department may at any time require a responsible entity to obtain or develop, within a time frame specified by the Department, information to fill one or more of the information gaps identified in the Final AA Report, under section 69505.5(i)(2), if the Department determines this information is needed to re-evaluate, under section 69506.10(b), the initial regulatory response(s) imposed for a selected alternative or a Priority Product that remains in commerce.” § 69506.2(b).

Conducting an alternatives analysis is expected to be an expensive endeavor. In addition to being required to hire a “certified assessor,” businesses will be required to invest considerable resources to obtain the information in its supply chain to furnish the Department with potentially two different alternatives analysis reports. It is critical that they know and understand in advance what will be required of them and the requisite level of effort and cost they must expend in order to be in compliance.

It is essential that the Department put guidance on how regulated entities must complete an alternatives analysis in the Proposed Regulations and clearly define compliance so that CalChamber members can understand what will be expected, and can provide meaningful input to the Department, plan and invest accordingly.

What criteria will be used to determine what potential regulatory actions will apply to me?

Similarly, the Proposed Regulations lack objective criteria on which to understand how and when particular regulatory responses might apply to them. For the most part, the key criteria for selection are subjective findings that will be made in the future on a case-by-case basis. The range of regulatory responses that may be applied to a regulated entity under vague criteria, such as “if the Department determines” (see, e.g., §§ 69506.3, 69506.6) and “the Department may impose” (see, e.g., §§ 69506.5, 69506.7, 69506.9, 69506.10.) Even more disconcertingly, the Department has given itself unfettered discretion to change its mind.

“The Department may periodically re-evaluate any regulatory response imposed under this section to determine if changes are needed based upon changed circumstances or information identified since a regulatory response was selected, including information that fills one or more of the information gaps identified in the Final AA Report under section.” § 69506.10(b).

The range of regulatory responses is overbroad and beyond the authority provided in the statute. DTSC does not have the authority to impose many of the regulatory responses identified in this Proposal such as requiring businesses to post financial guarantees or bonds to provide for the long-term disposal of their products, or requiring them to

compensate retailers or local government for their role, if any, in disposal of those products. Also, the Department appears to be giving itself in this Proposal authority to regulate commerce in ways that are not related to the statute's purposes. For instance, among the range of options it lists for itself is the ability to impose: "[r]estrictions on the settings in which a product may be sold or used" and "[r]estrictions on who may purchase and/or use a product." See § 69506.5(b), (d).

It is unfortunate that the Proposed Regulation does not meet the basic requirements of the APA. The green chemistry enabling statute, the APA, the California Environmental Quality Act (CEQA) all require the Department to provide certain sets of basic information so that stakeholders can understand how Proposed Regulations will impact stakeholders, the economy, and the environment. The Department cannot ignore these requirements or defer them to a later date.

The APA requires a thorough fiscal and economic analysis, among many reasons, to help the agency craft the best regulations possible and to ensure that regulations are clear, necessary and legally valid. Due to the failure of DTSC to meet its APA obligations to assess the potential fiscal and economic impact of the Proposed Regulations, the California Foundation for Commerce and Education commissioned an independent study to assess the impacts on the economy. (Attached as Exhibit C.) It found the potential net costs to California businesses and consumers could reach \$150 billion in the first 25 years of the Proposal's implementation and could lead to as many as 123,000 direct lost jobs at the peak of implementation.

The lack of clarity in this Proposal and the lack of any of the required economic and environmental analyses by the Department is more than an oversight. These important requirements are also more than just an academic exercise. True fiscal, economic, multimedia and environmental analysis must be complete and accurate to create the best regulatory program possible. Without this comprehensive analysis, the public cannot have faith that DTSC developed the best solution for California. Rather than blindly press forward, DTSC must go back to the drawing board and meet its obligations under the current law.

Justice Anthony Kennedy, in the recent U.S. Supreme Court case, FCC. v. Fox Television Stations (June 21, 2012), finding certain FCC regulations void because they were unconstitutionally vague, stated:

A fundamental principle in our legal system is that laws which regulate persons or entities must give fair notice of conduct that is forbidden or required. . . . This requirement of clarity in regulation is essential to the protections provided by the Due Process Clause of the Fifth Amendment. . . . It requires the invalidation of laws that are impermissibly vague. A conviction or punishment fails to comply with due process if the statute or regulation under which it is obtained "fails to provide a person of ordinary intelligence fair notice of what is prohibited, or is so standardless that it authorizes or encourages seriously discriminatory enforcement." . . .

As demonstrated in this letter, the Proposal does not currently provide fair notice of what will be required of those subject to its provisions. The Department needs to suspend this Proposal and go back to the drawing board. The Department needs to do all the analyses required by the APA, CEQA and the enabling statute to inform itself and the public of economic, multimedia and environmental impacts of its Proposal. Then based on those analyses, craft a new revised proposal that is clear in its requirements and is the least restrictive alternative to achieve the statute's purposes. And above all, the new proposal must give fair notice to all persons reading it of the answers to the critical questions we raised at the outset: :

- What chemicals that I use will be regulated?
- What information, data and studies will be required of me?
- What products that I make, sell or import will be regulated?
- How do I perform an adequate alternatives analysis?
- What criteria will be used to determine what potential regulatory actions apply to me?

We look forward to assisting the Department as it reconsiders and revises its Proposal. Should you have any questions, please feel free to contact me at 916-444-6670.

Sincerely,



Jeanne Cain
Executive Vice President, Policy

Attachments:

- Exhibit A: *Letters Seeking Clarification on APA Process: CalChamber to DTSC dated August 20, 2012/DTSC to CalChamber dated September 10, 2012*
- Exhibit B: *CalChamber Letters to DTSC dated December 30, 2011, November 1, 2010, and July 14, 2010*
- Exhibit C: *California Foundation for Commerce and Education Economic Study dated October 8, 2012*
- Exhibit D: *OEHHA Regulations, Green Chemistry Hazard Traits for California's Toxic Information Clearinghouse, Chapter 54, 22 CFR § 69401 et seq.*
- Exhibit E: *Letter from Senator Rubio and Legislators to Governor Brown dated October 1, 2012: DTSC Response Letter to Senator Rubio dated October 5, 2012*

GCREgs@DTSC

From: Ferhut, Faridoon <Faridoon.Ferhut@CalRecycle.ca.gov>
Sent: Thursday, October 04, 2012 4:05 PM
To: GCREgs@DTSC
Subject: CalRecycle's Comments on the Safer Consumer Product Regulations
Attachments: End-of-Life Management Requirements Sept. 2012v2.docx

Dear Ms. Von Burg,

CalRecycle's comments on the Safer Consumer Product Alternative Regulations, Section 69506.8., End-of-Life Management Requirements, are in the attached file.

Thank you for the opportunity to review and comment on the regulations. We will gladly answer any questions you may have and look forward to the successful implementation of Green Chemistry. I can be reached at: 916-341-6482

Regards,

Farheed Ferhut
Statewide Technical & Analytical Resources
California Department of Resources Recycling & Recovery (CalRecycle)
1001 9 Street, P.O. Box 4025 Sacramento, CA 95812
Phone: (916)341-6482
Fax: (916)319-7313
faridoon.ferhut@calrecycle.ca.gov

§ 69506.8. End-of-Life Management Requirements.

(a) Except as provided in section 69506.3, a responsible entity for a selected alternative, or a Priority Product for which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life, shall ensure that the following requirements are met:

(1) The information required by section 69506.4 shall be provided for the product. Additionally, the product information must state that the product must be disposed of or otherwise managed as a hazardous waste at the end of its useful life.

(2) No later than one (1) year after the Department issues a notice of compliance for the Final AA Report for the product, the responsible entity shall fund, establish, and maintain an end-of-life management program for the product. The program must comply with all of the following requirements:

(A) A comprehensive product stewardship plan must be developed and maintained, after being submitted to the Department for approval. The plan must include all of the following:

1. A list of, and contact information for, participating manufacturers, importers, and other participating persons.
2. The scope of products to be covered by the plan.
3. The roles and responsibilities for manufacturers, importers, retailers, consumers, and government throughout the life cycle of the product, and identification of retailers who have agreed to participate in the program.
4. Identification and description of collection systems that will be used.
5. End-of-life management information, that includes the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse multimedia impacts.
6. Anticipated resources needed to implement and sustain the plan, including identification of any third-party product stewardship organization collecting and administering a fee to fund the stewardship program.
- 7.a. A financial guarantee provided by the responsible entity to insure a sustainable end-of-life management program for the product.

b. "Financial guarantee" means any mechanism, including the mechanisms described in article 8 of chapter 14, to ensure that adequate funding is available to pay for future

Comment [FF1]: CalRecycle is concerned that "financial assurance" is unclear and may not provide the level of assurance that would be adequate.

end-of life management costs for products placed into the stream of commerce in California.

8. Program performance goals, which shall be quantitative to the extent feasible, for:

a. Increasing the collection, reuse and/or recycling rate of covered products at the end-of-life; and

b. Increasing **recyclability**.

Comment [A2]: Recyclability is not the same as increasing recycling. Include both?

9. A description of how each program goal will be achieved.

10. Public education, outreach, and communications plans.

11. A description of public and stakeholder consultation activities during preparation, and in periodic review and updating, of the plan.

12. Reporting and evaluation procedures.

(B) The product stewardship program and plan for collecting and, if applicable, recycling the product shall be developed in consultation with California retailers and owners/operators of prospective collection sites. The collection program must include one or both of the following:

1. Collection mechanisms; and/or

2. Compensation to retailers and other persons who agree to administer or participate in the collection program.

(C) The responsible entity shall provide its product stewardship plan to the Department for review and **approval**, **post a copy of the product stewardship plan on its own website**, and provide a link to the posting to the Department for posting on the Department's website.

Comment [FF3]: DTSC should carefully consider if more specific language will be needed to ensure quality plans are submitted. An example of a quality plan is Carpet America Recovery Effort (CARE)'s plan submitted to CalRecycle. CARE is a stewardship organization for carpets. This plan can be found on the following website: <http://www.calrecycle.ca.gov/EPR/Carpet/default.htm#Stewardship>.

(D) The responsible entity for a product subject to the requirements of this section shall ensure that a report is provided to the Department annually from the date the end-of-life management program is required to be implemented. **The report must include**, by total tonnage:

Comment [A4]: Report should mirror what is required in the plan.

1. The quantity of products placed into the stream of commerce in California over the previous **one-year period**; and

Comment [A5]: If there are many programs they each could have a different due date for their annual report, may administratively be challenging.

2. The quantity of products recovered over the same one-year period.

(b) Multiple responsible entities may form a third-party product stewardship organization, funded by participating manufacturers and other responsible entities, to

provide local services to collect, recycle, or otherwise appropriately manage covered products at the end-of-life.

(c) A responsible entity subject to the requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. A responsible entity may not substitute an alternative end-of-life management program for the program specified in this section unless it receives advanced written approval from the Department.

(d) A responsible entity subject to the requirements of this section may request an exemption from the requirement to provide an end-of-life management program by demonstrating to the Department's satisfaction in the Final AA Report that an end-of-life management program cannot feasibly be implemented for the product.

NOTE: Authority cited: Sections 25253 and 58012, Health and Safety Code. Reference: Section 25253, Health and Safety Code.



October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

The Chemical Industry Council of California¹ (CICC) appreciates this opportunity to comment on the Proposed Safer Consumer Products regulation. CICC was among the industry organizations that supported the enabling statutes of these Proposed regulations, AB 1879 and SB 509, when they were passed in 2008. Since that time we have actively engaged with both the Department and with the Green Chemistry Alliance, the industry coalition through which detailed comments have been provided regarding the various iterations of implementing regulations.

That history makes us very sensitive to the time and effort already expended in pursuit of final regulations. Unfortunately, it is our desire to ensure that these regulations are implementable and fulfill the spirit of the enabling statutes that leads us to reluctantly conclude that DTSC must **reconsider the fundamental direction being taken in these Proposed Regulations.**

To that end, we offer the following comments. These comments are not comprehensive in their scope. Rather, they are intended to highlight the rationale for this position, focusing primarily upon:

- The scope of the proposed **Chemicals of Concern** definition and its implications;
- The **prioritization processes** by which DTSC proposes to develop the list of Priority Products upon which action (via Alternatives Analysis) is to be taken; and
- The uncertainty and overreach driven by the extraordinarily limited **exemption criteria.**

Other aspects of this proposed regulation also remain of serious concern to us. We encourage full consideration by DTSC of comments to be offered on these sections by other trade associations and

¹ The Chemical Industry Council of California is a voluntary trade association comprised of large and small chemical manufacturers, distributors and allied businesses throughout California representing 105 facilities, with annual sales in excess of \$3 billion; employing more than 5700 workers with combined annual payroll \$283 million. An additional 11,000 indirect jobs are created by CICC member companies, with a combined annual payroll of some \$360 million.

Chemical Industry Council of California

companies that have participated in the Green Chemistry Alliance (GCA), and which we know to be addressing these issues in more depth. The other issues of particular concern continue to include:

- Alternatives Assessments;
- Accreditation Bodies and Certified Assessors;
- Regulatory Responses; and
- Trade Secrete Protection.

We have always known that this is a pioneering effort and that the crafting of regulations to enable its reasonable implementation would be difficult. We appreciate your consideration of our concerns. For further information or questions regarding the Chemical Industry Council of California, its members, or the attached comments contact Thomas R. Jacob (916) 782-1266 or John Ulrich (916) 989-9692. You may also visit the CICC website at www.cicc.org. Thank you!

Sincerely,



Thomas R. Jacob
Sr. Consultant/ Lobbyist
Chemical Industry Council of California



John R. Ulrich
Executive Director
Chemical Industry Council of California

Attachment

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

ATTACHMENT 1

COMMENTS OF THE CHEMICAL INDUSTRY COUNCIL OF CALIFORNIA
ON THE
PROPOSED SAFER CONSUMER PRODUCTS REGULATION (JULY 2012)

Chemical Industry Council of California (CICC)
October 11, 2012

GENERAL CONCERN: UNDERMINING THE PROMISE OF THE GREEN CHEMISTRY LAWS

Green Chemistry Laws of 2008: Many in industry, including the CICC, supported the Green Chemistry laws of 2008 (AB 1879 and SB 509), and still support the basic intent we saw embodied in them. We could read into their structure an accommodation of the fundamental reality of chemistry – namely, that chemicals have properties (“traits” in the parlance of the Proposed Regulation) that, if not managed carefully, can pose hazard. But it is precisely those properties – those “traits” of concern here - that enable chemistry, properly managed, to be harnessed and yield extraordinary societal benefit.

These laws were preceded by a lengthy history of legislative proposals in California and elsewhere, seeking indiscriminate chemical bans on one chemical or another, often based on superficial or very unsettled science – in essence, legislating the “chemical *du jour*.” That put Legislators in the position of arbitrating science, but with neither time nor capacity to really explore or understand the broader implications of these proposed actions.

These Green Chemistry laws foresaw a scientific rather than a Legislative process, and one aimed not at indiscriminate action, but rather a very targeted process enlightened by the principles of Green Chemistry² and Green Engineering³.

The vision was a systematic effort to have the State’s scientists filter through the myriad of chemical and product combinations to identify and focus upon those specific ones where the chemistry is not being adequately managed – to then isolate on those products posing the greatest threat, and subsequently compel systematic application of green chemistry and green engineering. The aim was to deliver the product’s utility while greatly reducing its threat – and thus to systematically ratchet down that risk associated with the greatest threats to our population and environment.

Distorting Focus of Current Proposal: This Proposed Regulation, however, upends that vision. It focuses compulsively on designating as many chemicals as possible as “Chemicals of Concern” – far more than the Department of Toxic Substances Control (DTSC) has capacity to evaluate in depth in the context of the enabling statutes. In both its insistence on its expansive “lists of lists” approach and in its steadfast refusal to consider an intermediate step of designating most of these as “Chemicals under Consideration” or the like, the Department has subordinated the goal of a very focused and systematic ratcheting-down of the greatest real threats, to the mistaken notion that any chemical with a hazard can be substituted-for to the benefit of society.

The Initial Statement of Reasons (ISOR) issued for the Proposed Regulations implies a clear aim of the Department in designating such a huge list of Chemicals of Concern is to send a blanket signal to the marketplace that the State of California declares use of all these chemicals to be inherently problematic. The fact that the State of California, with its substantial scientific resources, is making

² Green Chemistry is articulated most notably in Green Chemistry: Theory and Practice, Anastas, P.T. and Warner, J.C., Oxford University Press; New York; 1998

³ Green Engineering is articulated most notably in “Design Through the Twelve Principles of Green Engineering, Anastas, P.T. and Zimmerman, J.B., Environmental Science and Technology, volume 37; 2003.

such a sweeping pronouncement will *de facto* grant countless self-appointed advocates the imprimatur of the State in challenging any products using those chemicals, regardless of the applications to which they are being put or the real risk associated with them, and regardless of whether they end up being central in a Priority Product. This is absolutely not in the interest of the people of the State of California.

This approach seems to lose sight entirely of the public interest in the utility and benefits yielded by application of the science of chemistry in countless materials and products enabled by those chemicals, often by the very properties (“traits”) at issue. The need to balance that societal betterment against the threats posed by the handfuls of products for which real threats are not being well managed seems to be largely ignored. The focus of these laws was not anticipated to be on a sweeping designation of thousands of “Chemicals of Concern” and deliberately sending market signals to inhibit their use. Rather, it was to isolate on those very specific combinations of Chemical of Concern and Priority Product deemed by the scientists of the State to be posing the greatest threat. To spread the alarmism of “Chemicals of Concern” across such a wide universe without any regard whatever for the consequences is simply irresponsible.

Additionally, the Proposed Regulation redirects major effort (not to mention significant bureaucratic burden) to preventing any conceivable potential for “unintended consequences” that may ensue from trying to use, substitute for or even trying to eliminate, chemicals on that broad list. This is carried to such an extreme that the use (and abuse) of the list itself threatens to induce sweeping, indiscriminate impacts on uses of those chemicals. Perhaps most importantly, any company contemplating R&D involving any of the Chemicals of Concern, whether prioritized or not, must confront the reality that the State of California can, almost on a whim, isolate on that use and draw them deeper into this bureaucratic net that potentially compromises any opportunity to deliver an innovative product to the marketplace, even those applying green chemistry and green engineering principles.

Implications of the Current Proposed Regulation: Any product that uses any of these designated Chemicals of Concern is potentially thrust into such a bureaucratic labyrinth. Instead of narrowly focusing on the real, major threats, the underlying impulse seems to be to declare these chemical properties (these “traits”) to be “bad” -- discouraging society from exploring the potential utility and benefits that could come from safely harnessing them. This confounds the potential for society to realize utility as a direct result of such unique chemical properties. Rather than directly reducing scientifically documented threats by green chemistry, this is indiscriminately inhibiting potentially enormous societal benefit by setting us on a path of discouraging the safe harnessing of chemical properties.

This is not enlightened “Green Chemistry.” This is taking the promise of a surgical scalpel targeting the most significant threats, and transforming it into a meat-axe that threatens indiscriminate market impacts without consideration of whether there are real threats. In the process it threatens the most significant unintended consequence of all: it would undermine the incentive to innovate by casting a potentially indiscriminate regulatory shadow over the opportunity to safely harness the properties of the natural world around us.

CHEMICALS OF CONCERN

“Chemicals of Concern” v “Chemicals under Consideration”: In establishing its initial list of Chemicals of Concern, DTSC has opted to take a “list of lists” approach, citing a broad mix of lists sourced from various bodies with little in common. The purposes of the lists are quite varied – some are purely scientific, some are regulatory, there is overlap in areas of focus among some and there are distinctly different areas of focus among others. There is no continuity among the lists, particularly with respect to the scientific rigor behind them. This “mish-mash” has little in common beyond the fact that each lists “chemicals.” DTSC proposes to take this list, which aggregates to approximately 4,000 chemicals, and cut it down to 1200 chemicals. These initial “Chemicals of Concern” will, in essence, be locked-into this potentially enormous, burdensome, and far-reaching regulatory initiative. Yet, contrary

to the direction of the enabling statutes, there is no identified, transparent process by which this filtering is to be done.

Even with that, the end-result of the approach being taken here is still an enormously expansive “list of lists” defining “Chemicals of Concern.” While it is correct that such expansive lists have been identified for other purposes elsewhere, these typically do not have regulatory implications. DTSC’s list, however, certainly does carry regulatory implications. This is a list of chemicals, any one of which could be prioritized to drive products containing it into the completely open-ended Alternatives Assessment (AA) regulatory process.

Of perhaps even greater concern, however, is the clear intent of DTSC, as expressed in the ISOR, that this list should “send immediate signals to the marketplace about chemicals subject to this program.”⁴ In essence, DTSC is proposing to subject this entire list of chemicals to a *de facto* public relations campaign to broadly discourage their use, without benefit of any further evaluation by the Department.

Designation of such an expansive list as “Chemicals of Concern” will be interpreted as labeling use of these chemistries as inherently problematic without any consideration of either the appropriateness or safety of the application being pursued. This is absolutely not the intent of the original laws, and given the disparate sources and lack of any clear process, neither is it legally defensible.

We believe the true intent of the laws can be restored and the lists put back into a more appropriate context with one simple change:

RECOMMENDATION #1: Reclassify the bulk of the listed chemicals to be exactly what they really are: “Chemicals under Consideration.” The regulations should reserve the classification of “Chemicals of Concern” for the specific subset of those chemicals that the Department chooses to evaluate further and upon which it chooses to focus in its priority-setting process.

Differential Standards among the Lists: The list of lists, generally, is problematic to the extent there is neither consistency nor continuity either among the source-lists or in some cases within them. There are differing foundations for the lists and differing standards of scientific rigor (e.g. the Proposition 65 list has recently introduced a number of chemicals which originate from a Labor Code process that is not at all comparable to the science behind the other Proposition 65 listings). In some cases inclusion of the lists raises questions regarding the standards being applied both now and in the future. The listing of chemicals from the Oslo and Paris Convention stands out, for example, as OSPAR is no longer maintaining that list, and as pointed out in comments relayed below, it did not meet reasonable criteria as an expert organization in the first place.

It is also notable that the Proposed Regulation provides no opportunity to challenge the legitimacy of the initial lists iterated. In cases such as OSPAR, or even the Washington State list, where provisions for its management are not clear, this raises a concern regarding the subordination of California regulation to scientific standards that may not be as rigorous as those that would be imposed within the State. This raises the question as to whether this list could in the future become a “back-door” to addition of chemicals that would not pass scientific muster in California, but which would become Chemicals of Concern, with regulatory implications, by virtue of inclusion in Washington (without specific regulatory implications).

On that latter point, it is ironic that DTSC has elected to defer to such questionable “authorities,” while at the same time stating explicitly in the ISOR: “*DTSC has precluded regulatory authority over the consumer product by a foreign country, another state or a local agency to qualify for the statutory exemption since in these situations there is no jurisdictional or consistent authority either in or*

⁴ “Initial Statement of Reasons: Safer Consumer Products”, Department Reference Number: R-2011-02
Department Reference Number: R-2011-02, page 57

throughout California."⁵

By ignoring this stance when it is selecting its initial list, DTSC is, in essence, allowing the mere listing of a chemical by these particular outside agents to dictate its inclusion in a regulatory listing for California. This, unfortunately, reinforces growing concern in some quarters that DTSC is not motivated to assure the scientific integrity of the lists (the quality of the "authoritative bodies"). It instead triggers the fear that the desire is simply to secure un-appealable "Chemical of Concern" status (or a less-rigorous future route to such status) for certain chemicals included on those lists that would otherwise be questionable, even where the science may not support it.

This surely cannot be the intent of DTSC. We therefore urge the following considerations in revising the lists to which DTSC will look in considering chemicals for potential consideration as Chemicals of Concern:

RECOMMENDATION #2: The lists considered initially should be restricted to those which are clearly established forums of national and international renown, recognized as centers of scientific expertise in their respective areas. These must also have rigorous standards for curation. Neither OSPAR nor the Washington State lists would seem to fit. Beyond this, we would endorse the more detailed iteration of recommendations on lists offered by the Grocery Manufacturers Association in their comments on the current Proposed Regulation:

- *(1)(C) is the European Union's endocrine disruptor list. This should be dropped as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input. The list was discredited by the EU's scientific advisors. The objective in creating the list was to identify chemicals that deserved further investigation on whether they are endocrine disruptors, but that was never done and there has been no EU regulatory attention to the list for 5 years.*
- *(1)(H) is Canada's prioritization list of potential PBT compounds, mostly based on modeling and completed in 2007. Since that time Environment Canada has conducted hundreds of assessments in its Chemical Management Program leading to determinations in a number of cases that a chemical is not in fact PBT. The Department should adopt its Chemical of Interest and Chemical of Concern lists utilizing the most up-to-date information.*
- *(1)(I) is IARC's Carcinogen list. GMA strongly disagrees with inclusion of 2B substances, as the evidence level is less than that of other international Carcinogen sources.*
- *(1)(L) is the Office of Health Assessment and Translation reproductive and developmental toxicants. GMA agrees with this source, but notes that chemicals included in the Green Chemistry program should be those identified as Serious Concern and Concern.*
- *(2)(F) is the California Biomonitoring program, where numerous chemicals have been listed, some of which are beyond those tested in the CDC Biomonitoring program. The California program is in the early stages, and little testing has been completed and validated. None of the chemicals that are beyond CDC's studies and which have not yet been studied in California's program should be considered to have "exposure information" under this regulation.*
- *(2)(H) is the OSPAR list of substances for priority action. This should be dropped as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input.*

⁵ "Initial Statement of Reasons: Safer Consumer Products", Department Reference Number: R-2011-02
Department Reference Number: R-2011-02, page 95

Scientific Foundations of Chemicals of Concern Listing: The fundamental choice, here, to incorporate a “list of lists” as the initial starting point for defining “Chemicals of Concern” would not be a problem if that was merely an initial step in a public process to further evaluate those chemicals before defining a much smaller subset as that upon which the Department would focus as “Chemicals of Concern” (see Recommendation #1, above). That would properly signal this initial list as the starting point for the application of the State’s science to identify the specific combinations of chemicals and products that pose the greatest threat.

That, of course, is not what is being done. DTSC is choosing to designate a very large number of chemicals as Chemical of Concern with the express intent to discourage use of those chemicals, whether or not they are ultimately associated with Priority Products. That operational intent is beyond the intent of the law and raises serious questions regarding the criteria by which DTSC selected and will filter the lists in question. While the ISOR indicates DTSC will be culling the listed chemicals in various ways (to get to their total of around 1,200), the process is not at all transparent, and contrary to direction of the enabling statutes, offers no opportunity to question the specific rationale for particular chemicals.

It is imperative that the initial judgment of a chemical possessing a particular hazard trait be founded on the strongest possible evidence. Failure to establish this link to hazard traits on such a strong foundation risks misdirecting major resources of the State and the private sector, to say nothing of potentially denying society utility of chemical uses that may mistakenly be called into question. The Proposed Regulation at this point contains no express standards for that judgment.

Significantly, for many of the hazard traits being focused upon, OEHHA has iterated explicit criteria for judging the strength of the evidence for a chemical possessing such traits. As GCA noted in their comments of January 13, 2012, on the Draft for Public Comment of the Safer Consumer Products regulation:

The criteria specified by OEHHA as constituting “strong evidence” are those that typically provide the most direct indications that a hazard trait (or endpoint) is, indeed, linked to or operative with a specific chemical in a causal way or with a strong preponderance of the weight of the evidence. “Suggestive evidence”, on the other hand, is typically used to describe positive but not definitive evidence of such relationships. Many of the tools or mechanisms listed as “suggestive” are screening tools utilized to target follow-up analysis that can establish more definitively whether the specific trait is, in fact, manifest. It is simply not appropriate to trigger such far-reaching consequences on the basis of admittedly less-than-conclusive information.

That would seem to be an appropriate minimum standard for any chemical selected for designation by the State of California as a Chemical of Concern. While the ISOR does have some general references to the strength of the evidence, the OEHHA distinction is nowhere spoken to directly in the Proposed Regulation.

RECOMMENDATION #3: The Proposed Regulation should incorporate an express standard to the effect that, for any hazard trait for which OEHHA has specified criteria for gauging strength of evidence, any chemical designated as a Chemical of Concern must be clearly documented to link to the subject hazard trait on the basis of “strong evidence,” per the OEHHA criteria.

PRIORITIZATION PROCESSES

The Narrative Approach: Many of the considerations discussed above, relate also to the additions to that Initial List, particularly those relating to transparency regarding the criteria utilized in selecting chemicals, and the demand for a standard of “strong evidence” linking any particular chemical to specific hazard traits. With the subsequent additions to the list, however, we run squarely into the

debate regarding prescribed criteria for identifying and prioritizing Chemicals of Concern, versus what the ISOR refers to as the “narrative approach.”

The Chemical Industry Council strongly supports the articulation of specific criteria and prescriptive process to guide DTSC in chemical selection and prioritization. Identification by the State of California as a Chemical of Concern is significant and it is intended to be so. With such a very broad array of “hazard traits,” any one of which could be grounds for thrusting a chemical into this CoC category, combined with the extraordinarily broad range of factors to be “taken into account,” failure to prescribe criteria and more specifically outline processes leaves an inordinate amount of discretion to the Department, with little accountability. That stands in stark contrast to the hyper-concern evidenced by the excessive and very highly prescriptive accountability demanded of industry. It is almost as if DTSC is seeking to avoid any accountability for decisions that are absolutely crucial to the purposes of these laws and to the fate of potentially countless products.

Further, according to the ISOR, the predominant rationale for so doing seems to be ensuring DTSC’s decisions can accommodate emerging science in defining Chemicals of Concern and prioritizing them. This rationale is of grave concern, because it implies that the listing of Chemicals of Concern may not be based upon established science. This possibility underscores the fears that under these Proposed Regulations, the enabling statutes will be ripe for abuse by the Department in naming Chemicals of Concern and prioritizing products containing them, based upon very limited and highly disputed science.

The reality is that many of the controversies regarding possible chemical hazard are in fact controversies at the frontiers of science; and they are typically occupying major scientific efforts globally in attempts to find resolution. It is presumptuous to think that DTSC scientists possess the knowledge to unilaterally resolve such frontier issues; and it would be wholly misguided under these laws to redirect the State’s resources to doing so, when their intent is so clearly to focus those resources on the more targeted quest for reduction of established threats.

The clear aim of the enabling statutes is ultimately to focus the State’s resources on a limited range of products that are determined to pose the most significant threat to the public and/or the environment. It is absolutely inappropriate to allow these resources to be focused upon products based upon a judgment that its chemicals pose significant hazard, if that fact is not clearly established by scientific consensus. To do otherwise is to divert resources away from such clearly established threats, to products and chemicals that may in the end, not pose such a threat.

This is the reason why any linkage to specific hazard trait should be based upon “strong evidence” and it is the reason why such judgments should be based upon prescriptions that assure a foundation of scientific consensus.

RECOMMENDATION #4: Revise the Proposed Regulations to clearly prescribe the considerations to be evaluated in identifying and prioritizing Chemicals of Concern, the relative weighting of those considerations and the processes by which they are to be applied in both identifying Chemicals of Concern and prioritizing them. The aim of these must be to ensure the strongest foundation of scientific consensus around these judgments that will be the foundation upon which major resources of both the State’s and the private sector will be invested.

Selection Criteria and Chemical-Specific Guidance: There are specific steps that can be taken to overcome the deficiencies of these Proposed Regulations in the realm of identifying (and in the so doing, prioritizing) Chemicals of Concern. The intent of using the list to send market signals implies an obligation for DTSC to be explicit regarding both 1) the rationale for selection of the chemical (the specific hazard trait in question) and 2) the conditions of use in which that chemical is most likely to be a concern. It is absolutely not consistent with the aim of the enabling statutes to allow the-Chemical of Concern listings to drive widespread, indiscriminate pressure against use of these listed chemicals,

regardless of the application or its threat. To the contrary, the aim of green chemistry is very targeted and the laws are very clear that it is to be focused upon the greatest threats to the public and the environment

One other relevant point regarding such prioritization is simply that the workload associated with defensible action magnifies geometrically if we are looking at thousands of chemicals and compounds versus tens or even hundreds. This further underscores the need to have a two-stage process to isolate on Chemicals of Concern. The universe of Chemicals under Consideration need not necessarily be driven to individual quantitative ends. However, once an array of Chemicals of Concern has been identified, the law clearly anticipates a process of relative (quantitative) weighting of both the Chemicals of Concern and the products associated with them, such that the focus in the end will be on those posing the greatest threat – clearly a quantitative judgment that will have to be defended in court.

RECOMMENDATION #5: DTSC must be more transparent with respect to the criteria being used to select and filter these lists. The GCA Comments of January 13, 2012, offered an appropriate framing of a process for screening from such an initial list of Chemicals under Consideration to a list of Chemicals of Concern:

1. *Clean up the merged lists—remove pesticides, pharmaceuticals, and other substances that are not chemical compounds to which the regulations apply.*
2. *Narrow the result from above to identify chemicals made or imported into the U.S. using EPA, FDA and other exposure information such as biomonitoring data;*
3. *Further narrow the result to chemicals used in consumer products in the U.S. using EPA, FDA and other information;*
4. *Publish the proposed Chemical of Concern list for comment.*
5. *Finalize the list.*

We would add that:

- That final narrowing should reflect the handful of chemicals on which DTSC has decided to concentrate and from which the Priority Products will be selected;
- Once the selection of Chemicals of Concern has been made, DTSC must document for each chemical for purposes of general guidance:
 - The specific rationale for the listing; and
 - The types of uses where that would be of greatest concern (those they will be exploring in pursuit of the specific Priority Products upon which they will ultimately focus).

Quantitative Prioritization of Products: As with the identification of Chemicals of Concern, DTSC has again chosen a “narrative approach” for the selection of Priority Products containing a listed Chemical(s) of Concern. The proposed approach starts with a broad universe of Chemicals of Concern and factors to be taken into account by the Department. To be sure, the Proposed Regulation does mandate consideration of both hazard and exposure – a major step – and refined the text to address several other issues. At the same time, it continues to allow the equating of a chemical’s presence in products, market volumes and the like, with “exposure” – a very serious issue. The process for reconciling the various elements remains largely a “black box.” This is wholly inappropriate and can lead us right back to a *chemical du jour* environment. It will simply not provide any guidance regarding relative levels of concern and will be ripe for legal challenge.

This approach will not do justice to aim of the enabling statutes. The prioritization must be the product of quantitative considerations that can be readily understood and defended. This must be aimed not only at documenting the nature of the hazard attendant the particular Chemical(s) of Concern in the product (and ensuring that it is, in fact, associated with the chemical in question), but also documenting

the level of any “reasonable and foreseeable exposures” justifying the prioritization. If DTSC cannot be explicit about these considerations, then it is simply not doing justice to the intent of these laws. Indeed, the whole point of focusing the Department on “reliable information” is to ensure the ultimate provision of exactly such defensible information, and not allow the Department to prioritize either chemicals or products for reasons that are not defensible in court.

The need for applying more of a quantitative approach is underscored by the “Key Prioritization Factors” identified in § 69503.2 (b). DTSC has made these more meaningful in this proposal by narrowing them to just two fundamental considerations (ability to cause impacts and potential for exposure), and requiring priority to be given where both of them are met. However, in the end, both are meaningful only to the extent they are sufficiently quantifiable to enable relative comparisons. We would also reiterate the point that these Key Prioritization Factors should, in fact, be the initial screening point in the process of prioritizing products, not the final point, once the basic characteristics of the products have been determined.

RECOMMENDATION #6: The prioritization process must be founded upon relative comparisons enabled by quantifiable, defensible judgments of potential hazard for the public and/or environment of the Chemicals of Concern, and the reasonably foreseeable exposure potential of products associated with those chemicals. As a practical matter, this must include:

- A limited range of “Chemicals of Concern” for which defensible quantifiable judgments of potential hazard are made;
- A meaningful estimate of reasonable and foreseeable exposure or each product associated with these Chemicals of Concern which the Department has reason to believe pose a threat to the public or the environment; and
- A quantitative comparison to document the relative threat to the public or the environment among the chemical/product combinations.

Implicit in this is the need for some structured guidance regarding relative weighting across the very broad array of hazard traits, to say nothing of weighing reasonable and foreseeable public health versus environmental exposures. This quantitative step should be the initial filter for the process leading to the ultimate determination of Priority Products.

EXEMPTION CRITERIA

The Question of Jurisdiction: As the process advances to the stage of Priority Products, consideration must be given to the very specific admonitions of the laws’ directives that this regulation cannot 1) limit or supersede the authority of any other department, or 2) duplicate or adopt conflicting regulations for categories already regulated “for purposes consistent with this article.” This Proposed Regulation would apply a totally unreasonable standard to interpreting these prohibitions. Specifically, it would apply a standard of: *“the extent to which these other regulatory requirements address, and provide adequate protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.”*

It is significant that in defending this standard, the ISOR cites only the 2nd of those two prohibitions, and then proceeds to narrow drastically the notion of “consistency” to the point where the only possible exemption would be a law/regulation that duplicates virtually verbatim the Proposed Regulation. The more reasonable (and legally defensible) interpretation must also take into account the first prohibition, regarding limiting or superseding other authorities. In this regard the proposed regulatory interpretation falls far short.

Consider, for example, the authority over the workplace under both CalOSHA and its federal counterpart. They are charged with worker protection, including from harmful exposure to toxic substances. That mandate, however, is coupled with recognition of the workplace as a unique environment – one which often includes potential exposure to conditions inherently hazardous, but one which recognizes the necessity of moderating risk associated with those conditions by expert training and safety management, rather than total avoidance. If DTSC inserts itself in an arena in which the established regulatory authority does take into account the use of specific chemicals (including those DTSC deems to be Chemicals of Concern) in that overall risk-management balance, then DTSC is clearly encroaching on the authority of that agency. This manner of conflicting authority must be reconciled.

RECOMMENDATION #7: This Proposed Regulation must incorporate a higher standard to the effect that If another agency applies authority which legally and actively extends to the management of either specific Chemicals of Concern or specific products under consideration as Priority Products, such chemicals and/or products shall be exempt from this Regulation in that agencies area of jurisdiction, regardless of the manner in which said agency applies such authority.

Case-by-Case Threshold Exemption: DTSC in this draft abandoned consideration of a *de minimis* exemption. Instead, they propose a separate chemical-specific threshold determination for every Priority Product for each Chemical of Concern upon which the Priority Product determination is based. DTSC, in its ISOR, has stated that this “*will be primarily based on the minimum detectable concentration for the Chemical of Concern and the difficulty of avoiding the presence of contaminants.*” This is completely without foundation and generates a degree of uncertainty that undermines in the fundamental ways the integrity of the entire process.

As with the identification of Chemicals of Concern, the approach being taken here by DTSC seems oriented to allow the Department to establish regulatory jurisdiction based upon considerations that fall short of either established science or established regulatory policy. In surveying various regulatory authorities from EPA to the EU, to Canada and the like, the norm is clearly to establish a *de minimus* concentration level at 0.1%, unless there is specific science that warrants a higher or lower level.

The fact that DTSC refuses to consider such a normative standard and takes the extreme position of framing the threshold at detection limits effectively signals intent that the norm for this Proposed Regulation would be that nothing is exempt. This is not sound either from a scientific or a regulatory perspective, as it forces far more products to be evaluated under and AA process with no scientific justification – a waste of significant resources and potentially denying society legitimately safe products.

Additionally, the notion of defining such a threshold according to “available laboratory analytic methodology” renders it even more uncertain from the perspective of companies attempting to make future plans regarding use of products that may have trace levels of a particular compound (even when not intentionally added). What is “available”? Complicating this further is the express intent to revise these based upon new information, leaving open the possibility that every laboratory advance in “ability to detect” could end up rendering some products out of compliance.

Likewise on the exposure side, there is no established precedent for the position being taken by the Department with respect to “aggregate exposure” or “cumulative exposure.” The reality is that the science is not yet clear regarding the potential for such additive or synergistic effects. The issue of “aggregate exposures” raises serious questions of process and scientific underpinnings. It implies consideration of a simple “additive” notion of effects of such exposure, but this is not sorted-out in contemporary toxicology. Beyond that, it is, here, spoken of entirely independently of considerations of probable exposure from its use in the product in question. The same questions apply to the handling of “cumulative exposure” to other Chemicals of Concern in the product. Does this exist independent of

any consideration of the potential mechanism of such cumulative impacts? Does it exist independent of potential routes of exposure?

The matters above complicate enormously both compliance with and administration of the Green Chemistry laws, but promise little or no meaningful difference in terms of the ultimately level of threat- or risk-reduction to be achieved. The Department can easily remedy these concerns very simply, and return to the legislatively mandated focus of these regulations: to identify and systematically reduce the most significant threats to the public and the environment, by applying established scientific understanding.

Recommendation #8: The regulations should conform to contemporary scientific understanding and regulatory practice by:

- Setting a 0.1% *de minimus level* as the norm, unless the Department makes specific findings based upon contemporary science that a higher or lower level is appropriate;
- Excluding products where the chemical in question is not intentionally added;
- Considering only the specific Chemical of Concern in the specific Priority Product.

CONCLUSION

The Green Chemistry laws of 2008 promised an innovative approach to reducing chemical risk in contemporary society, while still enabling society to enjoy the enormous benefits of innovative uses of chemistry. To realize that vision, however, the regulations must respect the scientific reality that those benefits are enabled by the harnessing of properties of chemicals, not by avoiding those properties altogether.

The notion of a very focused effort, driven by science, to identify and systematically reduce risk associated with particular combinations of chemical properties and product use can liberate innovation to ratchet-down societal risk. The Proposed Regulation, however, would yank us back from that enlightened step. It would thrust us back into yesterday's policy world, dominated by distinctly unenlightened battles over broad arrays of chemicals and sweeping efforts to discourage their use. The result would be a squandering of significant public and private resources with little or no real impact on societal threats, but with distinct threats to the incentive to innovate by harnessing the properties of chemicals.

###



Public Works Department

October 8, 2012

DTSC
Office of Legislation and Regulatory Policy
P. O. Box 806
Sacramento, CA 95812-0806
Submitted via e-mail to: gcregs@dtsc.ca.gov

RE: Comments on Draft Regulations for Safer Consumer Product Alternatives

Dear Director Raphael:

The Environmental Services Section of the City of Chula Vista's Public Works Department has long been a supporter of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. As a founding board member of the California Product Stewardship Council, Chula Vista **supports the development of regulations that would promote the re-design of these problem products.**

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) **End of life management requirements** – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) **Municipality Costs - Add cost to municipalities as a prioritization factor.** Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,

Lynn France

Lynn France
Environmental Services Program Manager



October 11, 2012

Ms. Debbie Raphael, Director
c/o Krysia Von Burg
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Submitted via email to gcregs@dtsc.ca.gov

111 New Montgomery Street, Suite 600
San Francisco, CA 94105
415-369-9160 (P) 415-369-9180 (F)
www.cleanwateraction.org

Re: Safer Consumer Products Regulations

Dear Ms. Raphael,

On behalf of Clean Water Action, I wish to commend the Department of Toxic Substances Control (DTSC) for the years of hard work and dedication expended on developing the Safer Consumer Products (SCP) regulations mandated by the California Legislature under AB 1879 (Feuer). Clean Water Action has participated in the Department's stakeholder process since the beginning and has been impressed by the willingness of your staff to bring a wide array of voices to the table and to consider all points of view as part of their decision making. As with all such complex regulations, there are things that we believe can and should be improved. **However, on a whole we see the proposed SCP regulations as a positive step toward driving innovation that will result in safer products and economic growth.** We therefore urge DTSC to finalize and adopt the regulations with all expediency.

CWA is a national organization dedicated to ensuring that all people have access to clean water, a safe environment, and decision-making processes that impact the quality of their lives. We, and our over one million members (60,000 in California), see environmental protections as essential in and of themselves, as well as critical in protecting human health and safety. As wastewater, stormwater, and drinking water agencies struggle to address known and emerging chemical contaminants resulting from the use of products in the home and workplace, we find that too often these chemicals impair aquatic life and water quality, as well as threaten humans who drink the water, eat contaminated fish from polluted waters, and/or are exposed through recreation, tribal traditions, and other means. Consequently, environmental and human protections go hand in hand.

While we remain committed to the state's swift adoption of the SCP regulations, Clean Water Action is deeply concerned that environmental endpoints are not being prioritized to the degree that they should be.

The assurance that we consistently received from DTSC that environmental endpoints, including water and air quality, would be prioritized along with public health impacts such as

cancer and endocrine disruption has been a core reason for CWA's long-term commitment to the Green Chemistry Initiative stakeholder process and our support of the regulatory process. However, in reading the formal draft released for public comment, we find two issues that virtually ensure that important water quality and other environmental problems will not be addressed. We strongly urge the Department to rectify these serious flaws before formally adopting the rules.

1. Omission of California's 303 (d) list

Clean Water Action supports the regulation's robust list of Chemicals of Concern (CoCs) and DTSC's intent to not rank the chemicals on the list given discrepancies in the amount of data available on various substances and the difficulty in comparing the types of harm that they may cause. Given DTSC's commitment to a comprehensive CoC list, Clean Water Action and our allies in the water stewardship community were very surprised to find that California's 303 (d) list of impaired waterways and their related contaminants is not included. This is a serious omission that goes beyond the simple concern of which CoCs will be prioritized (such as human health impacts vs. environmental impacts). Without the 303 (d) list, the Department will not be able to even identify and take action on many key CoC/Priority Product combinations that impact aquatic ecosystems and/or cause water quality violations in California under the federal Clean Water Act and California's Porter-Cologne Water Quality Control Act. **For this reason, we strongly urge DTSC to add California's 303 (d) list to the list of lists by which CoCs will be identified and to review revisions made by the State Water Resources Control Board every few years.**

2. Section 69503.3(g)

Clean Water Action strenuously opposes Section 69503.3(g) which limits the CoCs considered when establishing CoC/Priority Product combinations for the first round of regulatory action. While this may not have been the intention, by requiring that the chemicals chosen in this first round must meet criteria described in both sections 69502.2(a)(1) and (2), DTSC is sending a message that environmental contaminants that do not appear on PBT and CMR lists are not a priority and can be easily disregarded. **This is not acceptable and we urge the Department to delete Section 69503.3(g) entirely.**

The reality, as we've mentioned in previous comments, is that there are no ecotoxicity lists for water and other environmental chemical contaminants that are equivalent to those for human health impacts. While chemicals that do comply with sections 69502.2(a)(1) and (2) may also contaminate water or other environmental strata, there are many that will not be initially eligible for action under the SCP regulations. This includes numerous "emerging" water contaminants for which there is evidence of harm to aquatic life, but little data on human health impacts. It also includes metals causing water quality violations in water. That these can be important to address is clearly demonstrated by the example of copper in brake pads. The environmental impacts of this chemical/product combination were considered so serious that the legislature took action to phase out the metal's use. Such a situation would not be addressed by the SCP regulations with the limitation that DTSC is proposing.

Clean Water Action respectfully disagrees with the argument that this restriction is temporary and thus acceptable. While we understand that the list of CoC/Priority Products to be acted upon in the first years of the program will be small, there is absolutely no reason for limiting the lists of chemicals and products from which DTSC will choose. In fact, it is our expectation that in order to set the appropriate precedents, at least one of the first combinations selected will respond to an environmental endpoint.

We have heard section 69503.3(g) justified as a way to provide manufacturers with some assurance as to what to expect initially. We do not see how this actually does this. What it does do, however, is take away assurances to the environmental and environmental justice communities, as well as local agencies who are responsible for complying with environmental standards that chemical/product combinations that interfere with meeting water quality requirements, impair aquatic life, or impact air will ever be chosen for regulatory action, unless a distinct connection to a public health impact can be made. This view is further substantiated by the fact that by omitting the 303 (d) list, the Department will be unable to address many critical water polluting chemicals.

Fortunately, rectifying these serious shortcomings is not onerous and can be done without delaying adoption of the regulations. That remains of paramount importance. As we said at the beginning of this letter, these regulations are the result of 4 years of discussion and input by a diverse groups of stakeholders. It is time to move forward and get the program up and running. Delay only diminishes the potential of the SCP regulations to fulfill their promise of safer products, economic growth founded on green chemistry based innovation, and job development.

Thank you again for the effort DTSC has made in developing these regulations and for considering our comments.

Sincerely,

A handwritten signature in cursive script that reads "Andria Ventura".

Andria Ventura
Toxics Program Manager



11 October 2012

Via e-mail GCRegs@dtsc.ca.gov

Ms. Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Draft Regulations for Safer Consumer Products, July 2012

Dear Ms. Von burg:

The Clorox Company, with headquarters in Oakland, California, is a manufacturer and distributor of many well-known and trusted consumer products. In addition to our namesake bleach and cleaning and disinfecting products, we have a stable of recognized brands including GLAD® wraps, bags and containers; Green Works® home care products; Pine-Sol cleaners; Fresh Step® cat litter; Kingsford® Charcoal; Hidden Valley® and KC Masterpiece® dressings and sauces; Brita® water-filtration products; and Burt's Bees® natural personal care products.

Product safety is a priority for Clorox. Indeed, all Clorox products are assessed for human and environmental impacts before making it onto store shelves, and ultimately, into consumers' homes. We maintain a rigorous, science-based assessment process to ensure our products are safe when used as directed.

We support the broad goals of the Green Chemistry Initiative and are committed to working with the Department of Toxic Substances Control (referred to as "Department" throughout this correspondence and other stakeholders to advance "green chemical" innovation while providing a safe, efficacious consumer experience.

In addition, our products meets or exceeds safety requirements of state, provincial or federal agencies that are charged with regulating those products, including, but not limited to the Environmental Protection Agency (U.S.), the Consumer Product Safety Commission (U.S.), the Occupational Safety and Health Administration (U.S.), the Food & Drug Administration (U.S.), Health Canada, Environment Canada, the California Air Resources Board, and the California Department of Pesticide Regulation. This robust regulatory backdrop does provide essential human health and natural resource protection. In fact, that is a key obligation of their activities and should be looked to for guidance in establishing a workable regulatory framework in meeting the Department's obligations under the Safer Consumer Products Act.

Clorox appreciates the opportunity to review and provide comments on the Safer Consumer Products proposed regulations (“the regulations”). Through our association with the Consumer Specialty Products Association (CSPA) as well as other industry efforts, we have been actively reviewing and providing our perspective to both the authorizing legislation and the long-term regulatory development process. In that vein, we align ourselves with the comments submitted by CSPA and industry colleagues, which provide a more comprehensive review of the points of concern. However, there are several areas of particular concern that Clorox would like to re-enforce concerns already raised.

General Comments:

We strongly concur with the view expressed by our industry colleagues that the proposed regulations could be enhanced if greater recognition was given to the requirements of the California Environmental Quality Act (CEQA) particularly the Economic Analysis requirement. The Department’s request for exemption from CEQA is not supported by the stated goals of the regulations as proposed. Of specific concern is the Department’s acknowledgement that “the need for additional CEQA evaluation will be considered at the appropriate stage of these regulations” while claiming there will be no effect. On its face, this is at odds with the objectives of CEQA and leaves the regulated community with a great deal of uncertainty as to the administrative procedure of this regulatory proposal.

We highly recommend the Department establish a comprehensive process, particularly around the development of priority listings and the Department’s identification of products or chemicals of concern. This puts manufacturers in an uncertain situation, further aggravated by the broad discretionary authority the Department is assuming in its approach. Manufacturers may also face potential “double jeopardy” with products that are already subject to review at the international, national and/or state/provincial levels.

We also strongly urge the Department to reconsider its approach to the protection of confidential business information (CBI). In light of the Department’s lack of experience in managing or securing CBI, and without any proposal to do so, the information proposed in Article 10 to accompany an assertion of trade secret status is, at best, overly ambitious. (Other state agencies, e.g. the Department of Pesticide Regulation, may provide a model for the Department to emulate.) Without greater security, including personnel trained in managing highly confidential information and supporting systems in place, we believe no more than a redacted version of the submission should be required.

Specific Comments

Article 2. Chemicals of Concern Identification Process

Section 69502.2(b)(1)(A)(8): This provision is problematic to the extent that degradents captures a suite of antimicrobial products that contain sodium hypochlorite as the primary active ingredient which can form chloroform/chlorines. In addition, it clouds the regulatory environment for products that are specifically designed to address indoor air quality concerns related to odor. Technologies designed for “through-the-air” application are being developed that contain oxidizing agents (i.e. sodium hypochlorite). This differs from the volatile organic compound (VOC) (or “degradents”) by-products alluded to in this provision in that the antimicrobial product itself would be in the vapor phase. How to account for degradation kinetics in the situation is not at all clear.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

Section 69503.2(a)(1)(B)(5)(3): This provision requires the Department to look at other state and federal statutes, as well as international agreements, to assess whether or not they afford sufficient protection with respect to public health and environmental impacts. Although pesticide products appear to be exempt by the authorizing statutes, this section gives the appearance of piercing that exemption along with the protection it provides against multiple regulatory reviews of chemicals/products -- notably without reference to further rulemaking.

Section 69503.3 (f)(1)(B): The inclusion of this language allowing a Governor's Executive Order to subvert existing priority setting provisions introduces a political element into what was envisioned to be a science-based approach for assessing chemicals/products that public health and environmental impacts.

Section 69503.5(c)(1)(B): This provision addresses the indoor air-quality concerns in both production and residential settings. As such, it is in conflict with air-quality criteria under the purview of the California Air Resources Control Board. In addition, it captures "off-gassing" that may be related to functionality of a consumer product. Capturing this "source" as a driver in establishing the "Chemicals of Concern" list as identified in Article 2 is duplicative and inappropriate.

Section 69503.2(a)(1)(B): Similar to the concern expressed immediately above, "...disposals, in any manner that would contribute to end-of-life impacts" captures materials designed for cleaning with a waste stream that terminates in a sewer environment (i.e. a publically-owned treatment works (POTWs)). This overlaps the jurisdiction of the State Water Resources Control Board and its regional boards, and poses another "double-jeopardy" situation for the manufacturer. It is recommended that this section incorporate existing statutory authority in the state's water code, by reference.

Section 69503.5: The alternatives analysis threshold exemption is disconnected from respected analytical methods used on an international basis. As noted by CSPA (and others), analytical chemistry continues to advance in its ability to detect compounds at increasingly lower levels; however, it is important to have an understanding of the RISK that detection might pose to human health and the environment. In and of itself, detection is not necessarily a threat, although it may suggest the need for further study and/or the data development. The Department's approach is to set this threshold on a case-by-case basis for each product, possibly below 0.01 percent and perhaps as low as the minimum concentration detectable. In contrast, the widely accepted global standard for triggering a regulatory intervention is 0.10 percent.

Article 5. Alternatives Analysis

Section 69505.1(c)(3)(A): The timelines proposed in this section are unreasonably short. For example, in our experience with the U.S. Environmental Protection Agency's (EPA) Design for the Environment (Def.) program, it can take as long as several years to identify/develop/register a new product with a sustainable profile when involving an alternatives approach to reformulation. We urge the Department to propose a more realistic timeframe that closely follows the U.S.EPA's experience.

Article 6. Regulatory Responses

Section 69506.5: While the imposition of use restrictions is common under regulatory schemes as FIFRA, the regulations need to provide a process that will allow for possible mitigation scenarios and/or the development of additional substantiating data.

Article 10. Trade Secret Protection

Sec. 69510(a)(3): The substantiating information that is being requested to accompany an assertion of trade secret status in this provision, while not uncommon, is overly ambitious given the Department's lack of experience in managing this type of information (in contrast to other agencies that handle trade secret information under an established process, i.e. U.S. EPA and CA Department of Pesticide Regulation.) Without greater security, including personnel trained in managing highly confidential information on a routine basis, providing a non-redacted version of the submission should only be required upon a judicial determination.

Conclusion

Clorox appreciates the opportunity to comment on the Department's proposed regulations implementing the Safer Consumer Product Act. We remain committed to working for a regulatory scheme that is legally defensible; allows for practical implementation; and is meaningful in meeting the spirit behind the authorizing statutes.

As others have also noted, the Department's outreach to the stakeholder community is appreciated; however, we believe it would serve California well to more tightly tie this regulatory process to a science-based, technically and economically feasible foundation that will provide an effective and sustainable model for other jurisdictions to emulate.

Please contact me at 925.425.6156, if you have questions regarding our comments.

Sincerely,



Mary-Ann Warmerdam
Regulatory Affairs Leader
Global Stewardship

Albany
Atlanta
Brussels
Denver
Los Angeles

**McKenna Long
& Aldridge**^{LLP}
Attorneys at Law

101 California Street • 41st Floor • San Francisco, CA 94111
Tel: 415.267.4000 • Fax: 415.267.4198
www.mckennalong.com

New York
Philadelphia
San Diego
San Francisco
Washington, D.C.

ANN G. GRIMALDI
(415) 267-4104

EMAIL ADDRESS
agrimaldi@mckennalong.com

October 10, 2012

**VIA E-MAIL (DRAPHAEL@DTSC.CA.GOV) AND
BY FEDERAL EXPRESS**

Debbie Raphael, Director
California Department of Toxic Substances Control
1001 "I" Street
Sacramento, CA 95812

Re: Comments of the Complex Durable Goods Coalition on Proposed Safer
Consumer Products Regulations

Dear Ms. Raphael:

I am pleased to submit the comments of the Complex Durable Goods Coalition (the "Coalition") on the proposed Safer Consumer Products Regulations released by the Department of Toxic Substances Control ("DTSC") on July 27, 2012 (the "Regulations"). We appreciate the extension of time DTSC granted to submit comments.

The Coalition is a group of trade organizations representing broad and diverse industry interests. Its mission is to engage in strategic planning, and regulatory and technical advocacy, regarding state and federal chemical initiatives, as such initiatives may impact the manufacturers of complex durable goods, their suppliers and other related entities such as those that may distribute or sell such goods and/or sell or use their service parts. For the Coalition's purposes, "complex durable goods" are manufactured goods composed of 100 or more manufactured components, with an intended useful life of five or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

Ten trade organizations comprise the Coalition, and membership continues to expand. Current members include the Aerospace Industries Association, the California Building Industry Association, the California Automotive Wholesalers Association, the Association of Home Appliance Manufacturers, the Outdoor Power Equipment Institute, the Truck and Engine Manufacturers Association, the Alliance of Automobile Manufacturers, the Association of Global Automakers, the Automotive Aftermarket Industry Association and the Motor and Equipment Manufacturers Association.

The companies represented by the Coalition are crucial to the economy of California and the nation. Aside from the economic contributions that flow from the sale and purchase of their goods, these companies in the aggregate directly provide hundreds of thousands of jobs in California and nationwide, and indirectly support the employment of millions of other individuals.

Notwithstanding the diversity of the Coalition's membership, Coalition members are uniform in their concern that the Regulations are overbroad, impractical and unworkable for manufacturers of complex durable goods, their suppliers and other entities which distribute, sell or use them and/or their service parts. Stated in the simplest way, the Regulations do not adequately account for the unique characteristics of complex durable goods. Among these unique characteristics:

- The global supply chain for these goods is multi-tiered and multi-faceted, from foundational raw materials to finished systems' components for final assembly and installation.
- The lead-time necessary for product design, development and validation is on the order of years, not months or weeks.
- These products are designed to last for several years, or in many cases, decades.
- Because these products are designed to last for years, service parts to support their repair and maintenance likewise must be available for years.
- These products already are subject to stringent legal, governmental and industry requirements, including safety standards.
- Changes in design and/or chemical composition nearly always require significant analysis, validation and performance testing. Such requirements can range from failure-mode analysis to actual field testing to specific methodologies of testing mandated by any number of regulatory outlets in the global markets in which products are sold. Timing, especially when prior regulatory approval is required, is unpredictable, potentially unachievable, and often in the magnitude of months and years, assuming that the chemical substitute even meets the performance criteria originally intended.
- These products must perform and function reliably in very specific ways.
- Consumers have specific expectations and requirements for these products.

Below I describe the Coalition's top concerns regarding the Regulations, and set forth the Coalition's proposed revised regulatory language and other recommendations to address those concerns.

Before turning to those top concerns, however, the Coalition joins in the comments of other entities pointing out the deficiencies in DTSC's economic impact analysis required under the California Administrative Procedures Act, and in DTSC's attempt to comply with the California Environmental Quality Act ("CEQA"). The Coalition agrees with those commenters that DTSC's analyses do not meet the legal requirements of those respective laws. The Coalition also points out that CEQA requires, among other things, an analysis of alternatives to the Regulations, yet despite the fact that DTSC has drafted numerous informal iterations of the Safer Consumer Products Regulations, DTSC has failed to analyze any of these. In these comments, the Coalition attaches and incorporates herein by reference two reports that discuss these analyses' shortcomings in greater detail: "The Consumer Impact of California's Green Chemistry Initiative," authored by the California Foundation for Commerce and Education and dated October 3, 2012; and the October 11, 2012 letter from Jim Lyons of Sierra Research.

The Coalition also joins in the concerns expressed by the Enterprise and Industry Directorate-General of the European Commission in the September 11, 2012 email communication from Mr. Giuseppe Casella to the TBT Enquiry Point of the United States (the "EU Comments"). That communication is attached and is incorporated herein by reference. As the EU comments point out, the Regulations are not even-handed and will not establish a level playing field among and within regulated industries. The Coalition agrees with the EU Comments regarding the inadequacy of DTSC's economic analysis, the limited time frame provided to responsible entities for conducting the complex alternatives analyses required, and the potential for conflict with the Technical Barriers to Trade Agreement.

I. TIME FRAMES FOR COMPLIANCE ARE WHOLLY INADEQUATE.

A. *Explanation of concern*

Complex durable goods require years of design, research and development, testing and validation. Changes in design and/or chemical composition affect each phase of the product lifecycle and require substantial lead-time: materials development alone can require five or more years, with design and development an additional four or more years, and potentially longer for aerospace products. Changes in design and/or chemical composition often require prior regulatory approval from other state and federal agencies. The timelines for such prior regulatory approvals are unpredictable, and potentially unattainable. Further, the supply chains for these products' raw materials and components are extremely complex. The Regulations must build in sufficient time to accommodate these challenges.

The time required to determine, for example, if the Priority Product contains the Chemicals of Concern ("COCs") at the Alternatives Analysis ("AA") Threshold (or, indeed, *any* level) will depend on whether the necessary information exists at the time the Priority Product is listed. If the necessary information is not available at that time, it could take several months to navigate through the complex supply chain network to obtain the necessary information. Even more challenging is the ability to make a decision regarding Priority Product removal or

replacement in the 60-day time frame established by the Regulations, for such decisions necessarily require the foundational knowledge, which takes time to obtain, that a Priority Product contains the COC. It would be virtually impossible for a manufacturer of a complex durable good to make a decision about Priority Product removal or replacement in that 60-day time period.

Further, the time to complete the extremely complex AA process is much too short. The EU Comments identify this problem in their comparison of the Regulations to the EU's REACH program. *See* EU Comments at p. 8. In addition, the time to complete an AA depends in significant part on how many alternatives are being analyzed. It takes little prognosticative ability to predict that the more alternatives are analyzed, the longer the analysis will take. Arbitrarily compressing the time frame to conduct the analysis could mean that alternatives that otherwise may be beneficial to human health and the environment will be discarded early in the process, to the detriment of the goals of AB 1879 and SB 509.

Regulated entities that manufacture complex durable goods also must be given sufficient time to build, test and validate prototypes. This process is time-consuming and resource intensive, and cannot feasibly be conducted on numerous alternatives. Moreover, entities must establish a reliable supply chain for the manufacture of complex durable goods; with new designs and/or chemical composition, establishing the necessary supply chain may require substantial time. The Regulations must accommodate the need for the prototype process and its timelines. The Regulations also must build in time to obtain necessary regulatory approvals following the prototype build, testing and validation process, so that the manufacturer may lawfully produce the final alternative. And, as part of implementing this prototype process, the Regulations must allow the Final AA report to make a recommendation regarding what alternative(s) will go through the prototype build, test and validate process, along with a recommendation regarding the time frame for such work, before any regulatory response is imposed.

DTSC can find an example of a regulatory approach that addresses the need for this post-AA process by looking to Washington State. Washington's brake friction material law requires a reduction of copper in brake friction materials, since the copper is released from the material during use and enters waterways, with the potential to harm aquatic organisms. Under the law, if Washington's Department of Ecology concludes that an alternative brake friction material may be available, it must convene a brake friction material advisory committee, consisting of representatives from industry, regulators and non-government organizations, and consult with that committee regarding the potential alternative. Revised Code of Washington ("RCW") section 70.285.040. Notably, and in obvious recognition of the lead-time necessary to test, validate and implement a change in brake friction material design and chemical composition, the law requires full implementation of the alternative *eight years* after the Washington's Department of Ecology concludes that a viable alternative exists, following its consultation with the advisory committee. RCW section 70.285.050.

The time frames for compliance under the Regulations are insufficient to accommodate the challenges described here. The Regulations must provide additional time for the initial notifications required to be submitted to DTSC, must build in more flexibility for the preparation and submission of the AA reports and work plans and must include a post-AA prototype testing and validation period prior to the imposition of any regulatory response, if one is to be imposed.

If, indeed, the goal of green chemistry is the design of new and “better” chemistries, the complex durable goods industry must be afforded sufficient time to develop them. And, as important as it is to avoid regrettable chemical substitutions that may adversely impact human health and the environment -- one of DTSC’s oft-stated concerns -- it is equally important to avoid regrettable *products* that do not provide the necessary functionality, durability, safety and other characteristics upon which users rely. The Coalition therefore urges DTSC to adopt its recommendations.

**B. Proposed revisions to regulatory language and timeframe recommendations
(additions in underline; deletions in strikethrough)**

1. *Revise Section 69503.4(g) as follows, with consistent changes in Sections 69503.7, 69503.6, 69501.2(b) and 69505.1(g):*

(g) Each responsible entity for a product listed on the Priority Product list shall provide to the Department one of the following notifications within ~~sixty (60)~~ one hundred eighty (180) days after the product is listed as a Priority Product, or ~~sixty (60)~~ one hundred eighty (180) days after the product is first placed into the stream of commerce in California, whichever is later:

* * * * *

2. *Revise Section 69505.2(c)(3)(C) as follows:*

(C) The work plan must be submitted to the Department no later than ~~sixty (60)~~ one hundred eighty (180) days after the product is included on the Priority Products list. Upon receipt of a work plan under this subsection, the Department shall follow the steps specified for the review of Preliminary AA reports in section 69505.6(a).

3. *Decouple the deadline for submitting the Preliminary AA Report, the Abridged AA Report and the Chemical of Concern Removal Notification, from the date the Priority Product list is published:*
 - a. The deadline for submitting the Preliminary AA report, the Abridged AA Report or the Chemical of Concern Removal Notification should be eighteen (18) months after the responsible entity submits the Priority Product Notification.
 - b. An extension of up to ninety (90) days should be made available as per Section 69505.1(d)(1).
4. *Revise the deadline for the Final AA Report:*
 - a. Section 69505.1(c)(3)(B):

Except as provided in subsection (d)(1), the responsible entity shall submit the Final AA Report no later than ~~twelve (12)~~ thirty-six (36) months after the Department issues a notice of compliance for the Preliminary AA Report....

- b. Section 69595.5(k)(1)(A):

The work plan and implementation schedule must specify the proposed submission date for the Final AA Report, and must ensure that the Final AA Report will be submitted to the Department no later than ~~twelve (12)~~ thirty-six (36) months after the Department issues a notice of compliance for the Preliminary AA Report.

- c. Section 69505.1(d)(1):

A responsible entity may request, and the Department may grant, a one-time extension of up to ninety (90) days to the submission deadline for ~~either the Preliminary AA Report or up to thirty-six (36) months to the submission deadline for the Final AA Report, or both.....~~

- d. Section 69505.2(c)(3)(D):

The due date for the Final AA Report shall be ~~eighteen (18)~~ thirty-six (36) months after the date the Department issues a notice of compliance for the work plan, unless the responsible entity requests, under Section 69505.5(k)(1), and the Department approves, under Section 69505.6(a)(3), a longer period of time. ~~The additional time shall not exceed thirty (30) months after the Department issues a notice of compliance for the work plan.~~

5. *Establish a post-AA prototype process:*
 - a. The Regulations must allow responsible entities to identify, in the Final AA Report, one or more alternatives that will undergo prototype building, testing and validation. In the Final AA Report, the responsible entity also would identify what other regulatory approvals are necessary for a successful prototype to be rolled out commercially.
 - b. DTSC would issue a Compliance Notification Regarding Prototype, and the deadline to complete the prototype process would be based on the date of the notification.
 - c. At least twenty-four (24) months must be provided for completion of the prototype process. In some cases, further development time may be required.
 - d. At the end of the prototype process, the responsible entity shall submit a Notification Regarding Prototype which identifies which alternative, if any, will be rolled out commercially and makes recommendations regarding regulatory responses, if any.

6. *Add new subsection in Section 69506:*
 - (d) No regulatory response shall be imposed on any product for which prototype building, testing and validation has not been completed and for which necessary regulatory approvals have not been obtained.

II. THE TERM “HISTORIC PRODUCT” IS TOO NARROW.

A. Explanation of concern

The Regulations’ current definition of “historic product” suggests that industry will be forced to make difficult choices regarding a limited amount of financial and human resources. Ultimately, AB 1879 requires DTSC to develop a prioritization process that adequately accounts for the risk and liability of products. The prioritization process should be transparent, objective and focused on the intent of the regulations, which includes economic feasibility.

As applied to the concept underlying the definition of “historic products,” service parts represent, in large part, components that are no longer being manufactured or distributed in significant quantities. Further, such service parts are predominantly associated with products that are no longer being actively manufactured. In essence, industry can either be forward-

looking and dedicate funds and human resources on research and development and making future products better, or it can go back and reinvent products that have little impact on human health or the environment. The latter is contrary to DTSC's oft-stated intentions.

The Regulations already, and appropriately, embrace the concept of exempting existing products by the definition of "historic products." However, the definition is too narrow to accommodate the regulatory realities of complex durable goods. In addition, the Regulations do not explicitly exempt spare parts for repair and maintenance of existing products. It is entirely consistent to include an exemption for service parts in the same spirit as "historic products" and for the same reasons. The definition of "historic" products therefore must be broadened, and service parts for such products must be explicitly included within the exemption.

B. Proposed revision to regulatory language

Revise definition of "historic product" in Section 69501.1(a)(22)(B)2 as follows (additions in underline; deletion in strikethrough):

"Historic product" means ~~a product that ceased to be manufactured prior to the date the product is listed as a Priority Product~~ one of the following:

(i) A product that ceased to be manufactured prior to the date the product is listed as a Priority Product; or

(ii) A product manufactured in accordance with a certification or approval by a federal or state regulatory agency or the Department of Defense prior to the date the product is listed as a Priority Product; or

(iii) A product that is used as a spare part or component for repair or maintenance of a product identified in (i) or (ii) regardless of when it was manufactured.

III. THE DEFINITION OF COMPONENT IS VAGUE AND UNCERTAIN AS APPLIED TO COMPLEX DURABLE GOODS.

A. Explanation of concern

Complex durable goods are composed of hundreds, even thousands of components, which themselves may be composed of many other components. In their current form, the Regulations acknowledge the difficulty in undertaking alternatives analysis on an entire complex durable good like a washing machine or a car. See Section 69503.4(a)(1)(B). But in order for the Regulations to be workable and provide predictability, the Regulations must be much more precise in defining what "components" may be identified in a Priority Product that is a complex durable product.

The Regulations also must be more specific about, and must limit the number of, “components” that may be identified in a Priority Product in a given time period, and must account for the cumulative impact, on the responsible entities charged with conducting AAs, of multiple component or materials listings. Alternatives analyses will be extremely complex, costly and time-consuming to undertake. DTSC’s proposed limit of ten components every three years is unworkable.

B. Proposed revision to regulatory language

1. *Revise Section 69503.4(a)(2)(B) to add new subsection 4 (addition in underline; with subsequent subsections renumbered accordingly):*

4. For purposes of subparagraph 2, “component” means a uniquely identifiable material within a single identifiable part or piece, not comprised of subparts, of a highly durable product.

2. *Revise second sentence of Section 69503.4(a)(2)(B)2 (addition in underline; deletions in strikethrough):*

For each listed highly durable product, the Department shall specify no more than ~~ten (10)~~ three (3) components ~~and/or homogeneous materials~~ per product every three (3) years.

3. *Strike the definition of “homogeneous material” in Section 69505.1, and remove all references to “homogeneous material” throughout the Regulations.*

IV. ANY REGULATORY RESPONSE TO BE IMPOSED MUST APPLY ONLY TO PRODUCTS MANUFACTURED DURING THE NORMAL MANUFACTURING CYCLE THAT BEGINS AFTER THE EFFECTIVE DATE OF THE REGULATORY RESPONSE.

A. Explanation of concern

Products identified as Priority Products may continue to be manufactured as they undergo the alternatives assessment process. Service parts for such products necessarily also must be manufactured -- not only during this interim period before the effective date of a regulatory response, if any, but also after the effective date of any regulatory response. That is because Priority Products that are complex durable goods will continue to be used, and will require service and maintenance, for years after their manufacture. The Regulations, however, fail to explain how regulatory responses will apply to such interim products and their service parts, thereby generating uncertainty in the regulated community.

The Regulations also fail to account for product manufacturing cycles, which typically manifest themselves as model years (for vehicles) or equivalents in other industries. Disruptions of normal manufacturing cycles are economically detrimental to the affected manufacturing entities and, ultimately, to the consumer.

Regulatory responses must be forward-looking and must not interfere with normal product manufacturing cycles. If DTSC expects regulatory responses to apply after-the-fact to such products and their service parts, DTSC will create a cumbersome, expensive and unworkable regulatory approach that will lead to substantial economic harm with no countervailing public benefit. Accordingly, the Regulations must ensure that regulatory responses will apply only to products, and the service parts of such products, manufactured during a product manufacturing cycle that begins after the effective date of the regulatory response, taking into account the necessary lead-time that manufacturers will require to implement any regulatory response.

B. Proposed revisions to regulatory language

Revise Section 69506.1 to add new subsection (b) (with subsequent subsections renumbered accordingly):

(b) Regulatory responses shall be imposed only on products, and the service parts of products, manufactured during the course of the manufacturer's normal product manufacturing cycle (e.g., model or model year) that begins after the effective date of the regulatory response, taking into account lead-time necessary for manufacturers to implement the regulatory response(s).

V. THE DEFINITION OF "MANUFACTURE" IS OVERBROAD.

A. Explanation of concern

The current definition of "manufacture" exempts repair, refurbishing and alteration activities, but unnecessarily narrows the exemption. The qualifying phrase in the definition that begins with the word "unless" will capture entities that have not been considered "manufacturer" in any other regulatory context and that very likely are ill-equipped to manage manufacturer responsibilities. This unnecessary narrowing of the "manufacture" exemption will result in confusion and uncertainty in the marketplace, ultimately to the detriment of California's economy by encouraging businesses, both large and small, to exit California for a more predictable business climate. At the same time, the Coalition sees no counterbalancing benefit to human health or the environment resulting from this expansive definition. The definition of "manufacture" should retain the exemption for repairs, refurbishment and alterations of consumer products, but DTSC must eliminate that qualifying phrase.

B. Proposed revision to regulatory language

Revise the definition of “manufacture” in Section 69501.1(a)(40) as follows (proposed deletion in strikethrough):

“Manufacture” means to make, produce, or assemble. “Manufacture” does not include any of the following actions, ~~unless the action results in the addition, or increased concentration of, a Chemical of Concern, or replacement in a Chemical of Concern, in a product:~~

- (A) Repair or refurbishment of an existing consumer product;
- (B) Installation of standardized components to an existing consumer product; or
- (C) Making non-material alteration to an existing consumer product.

VI. THE REGULATIONS IMPERMISSIBLY ATTEMPT TO SUPERSEDE AND/OR DUPLICATE OTHER REGULATIONS.

A. Explanation of concern

Health & Safety Code section 25257.1(b) prohibits DTSC from superseding the regulatory authority of *any* other department or agency. This section contains no other qualifying language. Health & Safety Code section 25257.1(c) separately prohibits DTSC from duplicating or adopting conflicting regulations for product categories already “regulated or subject to pending regulation consistent with the purpose of this article.” By separating the two concepts of superseding “any” other regulatory authority, on the one hand, and duplication/conflicting regulations, on the other, in Section 25257.1, the Legislature clearly expressed different concerns, and clearly intended any implementing regulations to account for these separate concerns.

But the Regulations gloss over this distinction and violate both of these prohibitions. The result is unnecessary and duplicative regulation that interferes with industry compliance with other regulatory schemes.

By focusing exclusively on Health & Safety Code section 25257.1(c), the Regulations do not adequately account for the existence of “the regulatory authority of any other department or agency” as required by Health & Safety Code section 25257.1(b). Further, the Regulations do not adequately address the prohibition contained in Health & Safety Code section 25257.1(c). These prohibitions should not be merely factors in Priority Product prioritization or in regulatory responses. Rather, in order to effectuate legislative intent, they explicitly should frame the applicability of the Regulations to exclude consumer products over which “any other department or agency” exercises authority and/or for which regulations already exist.

DTSC appeared to incorporate at least some aspects of this concept in its October 31, 2011 draft informal regulations. However, it is now far from clear that DTSC intends to abide by the prohibitions set forth in the authorizing statute. The Initial Statement of Reasons (“ISOR”) identifies an example of a “component” that DTSC may regulate: catalytic converters due to their ability to release nitrous oxide. ISOR at p. 22. This subject matter falls squarely in the realm of federal regulation under the Clean Air Act. Only the California Air Resources Board has been delegated authority in this area in California, and only to the extent allowed by federal law. Yet, the ISOR makes clear DTSC’s intent to regulate – impermissibly – in this area.

Absent clear language regarding the limits of DTSC’s authority, there is no reason to believe that DTSC would not improperly invade other areas of regulation. The Coalition urges DTSC to revisit its approach and adopt the revision set forth below.

B. Proposed revision to regulatory language

Revise to add new Section 69501(b)(4) (addition in underline):

(b)(4) This chapter does not apply to a consumer product that is regulated by one or more federal and/or other California regulatory program(s), and/or applicable international trade agreement(s) ratified by the United States Senate, to the extent that such other regulatory program(s) or international trade agreement(s) address(es) any of the factors identified in Health & Safety Code section 25253(a)(2)(A)-(M).

VII. THE DEFINITION OF “FUNCTIONALLY ACCEPTABLE” IS INADEQUATE.

A. Explanation of concern

The Regulations’ definition of “functionally acceptable” does not adequately address the unique nature of complex durable goods. As the Coalition explained in its testimony at the September 10, 2012 public hearing, complex durable goods are not the proverbial widget. Characteristics such as durability; safety (stemming from legal requirements and industry and company standards); performance consistent with product brand; consumer expectations with respect to the product brand; functional performance with respect to the product’s designated use; and aesthetics, including “look and feel” aspects of the product -- these all must be accounted for in the Regulations. Because the term “functionally acceptable” is critical in the prioritization of products, in evaluating alternatives and in the imposition of product sales prohibitions, the Regulations must be more comprehensive to be workable.

B. Proposed revision of regulatory language

Revise Section 69501.1(a)(31) as follows:

“Functionally acceptable” means that an alternative product meets ~~both~~ all of the following requirements:

(A) The product complies with all applicable legal requirements; and

~~(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.~~

(B) The product complies with all applicable safety standards in the relevant industry and with all internal safety standards implemented by the manufacturer of the product; and

(C) The product meets other applicable product criteria, taking into account the specific nature of the product and other relevant factors.

VIII. THE TERM “EXPOSURE” IN SECTION 69503.2 IS INCONSISTENT WITH THE SCIENTIFIC DEFINITION OF “EXPOSURE”

A. Explanation of concern

The Coalition is concerned that the criteria used in proposed Section 69503.2, to evaluate “exposure” in prioritizing products, erode the scientific concept of exposure to the detriment of the goals of AB 1879 and SB 509. The Regulations’ criteria of market presence, statewide sales and the like are inadequate surrogates for the scientific concept of “exposure.” Thus, the criteria in Section 69503.2 effectively break the link between the COC and the consumer product -- the link that is at the very core of what AB 1879 and SB 509 intend to target. Instead, the Regulations must incorporate the scientific concept of exposure -- *i.e.*, the fact that exposure requires the chemical to come into contact with, and be absorbed by, the body in some way.

B. Proposed revision to regulatory language

Revise Section 69503.2(a)(1)(B) to delete current subsection 1.a - b, and replace with the following (additions in underline; deletions in strikethrough):

~~1. Market presence information for the product, including all of the following:~~

~~_____ a. Statewide sales by volume;~~

~~_____ b. Statewide sales by number of units; and~~

1. Human exposures to the Chemical(s) of Concern in the product, considering:

_____ a. The amount(s) of the Chemical(s) of Concern in the product;

_____ b. The ability of the Chemical(s) of Concern in the product to come into contact with, and be absorbed by, the body of the intended user during reasonably foreseeable use of the product;

_____ c. The amount of time that the Chemical(s) of Concern in the product is/are in contact with the body of the intended user during reasonably foreseeable use of the product; and

_____ d. Intended product use(s), and types and age groups of targeted customer base(s).

In their final form, the Safer Consumer Products Regulations must be forward-looking in order to provide industry consistency with global regulations and implementation timing -- and, ultimately, in order to achieve the goals of AB 1879, SB 509 and, more broadly, the Green Chemistry Initiative. But in an attempt to craft a comprehensive chemical/product regulatory mechanism, California has pursued a course that not only makes compliance and enforcement unworkable, but also hinders other global efforts whose outcome would surely provide ancillary benefit to the State. Creating rules that make real-world compliance virtually impossible, combined setting with unrealistic expectations, perpetuates industry uncertainty and expenditure of resources that, in the end, fail to benefit the environment or the people of California. The Coalition urges DTSC to heed the Coalition's concerns and to incorporate the proposed revisions described above.

Debbie Raphael, Director
October 10, 2012
Page 15

Thank you again for this opportunity for the Coalition to comment on the Regulations.

Very truly yours,



Ann G. Grimaldi

Attachments

cc: Matthew Rodriguez, Cal/EPA Secretary (w/ attachments, via first class mail and email: matthew.rodriquez@calepa.ca.gov)
Cliff Rechtschaffen, Senior Advisor to Governor Brown (w/ attachments, via first class mail)
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor (w/ attachments, via first class mail)
The Honorable Michael Rubio, California State Senate (w/ attachments, via first class mail)
Odette Madriago, Deputy Director (with attachments, via email: omadriago@dtsc.ca.gov)
Jeff Wong, Chief Scientist (with attachments, via email: jwong@dtsc.ca.gov)
Kryisia von Burg, Regulations Coordinator (with attachments, via first class mail and email: gcregs@dtsc.ca.gov)



founded 1881

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

On behalf of the Consumer Healthcare Products Association (CHPA), a 131 year-old trade association representing the nation's leading over-the-counter (OTC) medicine and nutritional supplement manufacturers, I'd like to thank you for the opportunity to comment on the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Products Regulations (R-2011-02) ("proposal" or "regulation") of July 2012.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has invested in its latest effort to develop an efficient and effective regulatory environment which strikes a balance between concern for the environment and California consumers.

We, in concurrence with GCA, strongly recommend DTSC consider a program concentrating on the true risks for human health and the environment based on hazard, exposure and the likelihood of harm. Ultimately, CHPA strongly requests that OTCs be exempt from the regulations entirely.

**Consumer Healthcare
Products Association**
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org

OTCs should be exempt entirely from regulation.

The regulation of OTC medicines under the proposal is preempted by the federal Food, Drug, and Cosmetic Act (FDCA) and under regulations of the U.S. Food and Drug Administration (FDA).

Section 751 of the FDCA clearly preempts states from imposing additional regulation on OTC drugs, stating “no state may establish... any requirement (1) that relates to the regulation of a [nonprescription] drug...; and (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter...”¹

Furthermore, the language in the proposal is narrower than what is provided for in the implementing statute. Section 25257.1(c) of the California Health and Safety Code provides that “[t]he department shall not duplicate or adopt conflicting regulations for product categories already subject to pending regulation consistent with the purposes of this article.” Therefore, OTCs, which are regulated by the FDA and FDCA for the same risk being addressed under DTSC’s proposal, should *automatically* be exempted from regulation.

Applied to the OTC industry, the proposed regulation is clearly duplicative and conflicting. The safety of chemicals used in OTC medicines is regulated by the FDA through the approval of either a new drug application (NDA) or by conforming to a monograph issued by FDA. Through both processes, FDA approves a drug if, and only if, it proves to be safe and effective. Each monograph outlines detailed conditions to which the drug product must conform in order to be legally marketed, including identifying active ingredients, labeling statements, warning statements, and the like. Active ingredients that are included in a monograph have undergone extensive review for human health effects by experts in what is known as the OTC Drug Review. Through this assessment, FDA sets non-hazardous chemical levels and determines what is acceptable for use; any chemical formulation that does not meet this standard will not be approved.

¹ 21 U.S.C. § 379r(a). Section 751 permits state enforcement of requirements identical to those imposed under the FDCA. See 21 U.S.C § 379r(f).

As with all human drugs, the FDA already has authority to require an environmental assessment for OTC drugs (See 21 C.F.R. Part 25). Environmental assessments are part of the FDA's implementation of the National Environmental Policy Act, which ensures responsible stewardship of the environment for present and future generations, and enables the FDA to determine whether the proposed action may significantly affect the quality of the human environment.

Furthermore, the proposed regulation specifically requires the Department to consider the above mentioned laws when designating Priority Products. Since these laws undoubtedly ensure "adequate protections with respect to the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product," as required by Section 69503.2(a)(3) of the proposed regulation, OTCs should not be considered for Priority Product designation.

While Section 69506.11, "Exemption for Regulatory Response Requirements," permits a regulatory exemption from a requirement if it is in conflict with a federal program and the responsible entity could not reasonably be expected to comply with both, the FDA's NDA process and monograph requirements should obviate the need for inclusion in the regulation and subsequent burden of the exemption process.

Similarly, under the Dietary Supplements Health and Education Act, the FDA has several post-marketing responsibilities to ensure the safety of dietary supplements, including enforcement of the final rule on dietary supplement Good Manufacturing Practices (GMPs), released on June 25, 2007. This rule establishes uniform standards needed to ensure quality throughout the manufacturing, packaging, labeling, and holding of dietary supplement products.

OTC and dietary supplement manufacturers request regulatory certainty to ensure consistent product development and maintain quality and safety standards. These products provide real and significant health benefits to consumers at minimal costs. They are formulated and manufactured under extremely controlled environments that are also governed by FDA. Manufacturers of OTCs need the confidence that they will not be subjected to a patchwork of state requirements that could conflict with already existing federal obligations.

Subjecting these products to additional regulation could result in restrictions on ingredient use that is inconsistent with the federal determination. Thus, at a minimum, OTC drugs should be excluded from the scope of the proposed regulation for purposes of human health and environmental health issues. In addition, dietary supplements should also be excluded from the scope of the regulation.

Recommendation:

In order to explicitly exempt products already regulated by state and federal laws and prevent regulatory duplication and to remove the laborious, one-by-one exemption process, CHPA recommends adding the following section to the regulation:

§69501(b)(5): This chapter does not apply to product categories for which a Federal agency or another State agency has in place or pending regulations consistent with the purposes of §25251 through §25257.1 of the Health and Safety Code.

End-of-Life Management Requirements are Unnecessary and OTCs are Exempt under California Law

CHPA disagrees with the requirements laid out in Section 69506.8, End-of-Life Management Requirements. The vast majority of pharmaceuticals in the environment are from human use and metabolites of medicines – not from the improper disposal of medicines.² Consumers have more effective means of ensuring safe medicine disposal which not only protect the environment, but also prevent illegitimate access to drugs, decrease potential of abuse, and limit accidental poisonings.

Furthermore, the requirement pertains to products “required to be managed as hazardous waste in California,” which OTC products were exempted from under AB 1442³ which was signed by Governor Jerry Brown on September 27, 2012.

² Tischler, L. 2007. *Potential Contribution of Unused Medicines to Environmental Concentrations of Pharmaceuticals*, report to Pharmaceutical Research and Manufacturers of America, Tischler/Kocurek, Round Rock, TX.

³ California Assembly Bill 1442, sponsored by Assemblymember Bob Wieckowski. Chapter Number 689 of the 2012 Legislative Session. Effective January 1, 2013.

Disposal in household trash is the most convenient and environmentally responsible way to dispose of unused medicines. Proper disposal in household trash is environmentally responsible and more convenient for consumers than a product stewardship program, which increases the likelihood of compliance. CHPA supports SMARxT Disposal (www.smarxtdisposal.net), a campaign designed to educate consumers about proper disposal procedures for unwanted medicines, and the American Medicine Chest Challenge (AMCC). SMARxT Disposal is an initiative of the U.S. Fish and Wildlife Service, the American Pharmacists Association, and PhRMA and is in accordance with guidelines issued by the White House Office of National Drug Control Policy. The AMCC is a comprehensive public health initiative to educate the public about safe disposal and the dangers of medicine abuse, which gives consumers the choice of dropping off their unwanted medicines at a local collection site during a national take-back day, or at home using the SMARxT Disposal Program.

Trade Secret Protection must be less Arbitrary.

CHPA supports the inclusion of Trade Secret Protection in Article 10 Section 69510 as OTC and dietary supplement formulations are frequently trade secrets and in some cases patented. The proposal requires a producer or responsible entity to provide a significant amount of chemical and product data and information, as well as the quantity of intentionally-added chemical ingredients that CHPA believes is unnecessary and exceeds the scope of the statutory authority. CHPA opposes the submission of redacted copies required by this Article. Additionally, making the redacted copy available at the discretion of the Department is inconsistent with the provision in Section 69501.5(b)(6) where it says it “shall” put on its website “a full or redacted copy of each document.” We are also concerned that the proposal would allow DTSC to subjectively make determinations of the validity of a claim for trade secret. The regulation must include stronger safeguards and assurances that product formulations and trade secret information will be adequately protected.

In sum, CHPA believes that the proposal conflicts with and is largely duplicative of federal regulation of OTCs and should, therefore, exempt OTCs entirely. We urge DTSC to give serious review and consideration to these comments, as well as the comments submitted by the Green Chemistry Alliance.

CHPA appreciates the opportunity to contribute to the development of the Safer Consumer Product Alternatives Regulation. I am more than happy to speak to you about this issue at greater length and detail. Feel free to contact me directly at your convenience.

Best Regards,

A handwritten signature in blue ink that reads "Carlos I. Gutiérrez". The signature is written in a cursive, flowing style.

Carlos I. Gutiérrez
Director, State Government Affairs
CGutierrez@chpa-info.org

ckc



Representing Household & Institutional Products

Aerosol - Air Care - Cleaners - Polishes
Automotive Care - Antimicrobial - Pest Management

October 11, 2012

Via E-Mail - GCRegs@dtsc.ca.gov

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Proposed Safer Consumer Products Regulation (July 2012)

Dear Ms. Von Burg:

The Consumer Specialty Products Association (CSPA)¹ appreciates the opportunity to review and provide comments on the Safer Consumer Products Regulation. CSPA and our member companies have been actively engaged in the advance of California's green chemistry program over the past five years, from the announcement of the Green Chemistry Initiative, through the adoption of the 2008 legislation (SB 509 and AB 1879) which provides the statutory basis for this regulation, and through the years-long regulatory development process.

CSPA is a member of, and active participant in, the Green Chemistry Alliance, a group of major trade associations and companies that represent numerous broad industrial sectors in California. CSPA is also an active participant in the Alternatives Analysis Coalition, a group of major trade associations and companies that represents the industry perspective of the Alternatives Analysis Process. As such, CSPA supports comments submitted by the both the Green Chemistry Alliance and Alternatives Analysis Coalition. CSPA also supports comments made by sister trade associations which highlight additional relevant points of concern and urges the Department to **thoroughly** review and respond to each submission. In addition, the comments

¹ The Consumer Specialty Products Association (CSPA) is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution and sale of more than \$80 billion annually in the U.S. of familiar consumer products that help household and institutional customers create cleaner and healthier environments. CSPA member companies employ hundreds of thousands of people globally. Products CSPA represents include disinfectants that kill germs in homes, hospitals and restaurants; candles, and fragrances and air fresheners that eliminate odors; pest management products for home, garden and pets; cleaning products and polishes for use throughout the home and institutions; products used to protect and improve the performance and appearance of automobiles; aerosol products and a host of other products used every day. Through its product stewardship program, Product Care[®], and scientific and business-to-business endeavors, CSPA provides its members a platform to effectively address issues regarding the health, safety and sustainability of their products.

submitted by the European Commission are particularly persuasive and CSPA recommends that the Department strongly consider their suggestions, especially in light of the EU's experiences with trade and REACH.

CSPA members are committed to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. As stated in previous submissions regarding the Safer Consumer Products Regulation, CSPA and our members support the broad goals of the Green Chemistry Initiative and look forward to continuing engaging with the Department and other stakeholders in the state to help spur green chemical innovation and continue to ensure that products are safe.

CSPA member products are designed to improve the quality of human life and to protect the public against dangerous diseases, infestation, and unsanitary conditions. CSPA members are committed to providing products that are thoroughly evaluated for human and environmental safety and go through rigorous safety-based assessments before they are brought to market. CSPA members are also committed to clear and meaningful labeling on consumer products, *i.e.*, easily understood information to ensure safe and effective product use. CSPA has a product stewardship program called Product Care[®] that assists members in meeting these commitments. In addition, CSPA members are committed to the development of green products that are safe for human health and the environment. CSPA members routinely apply green chemistry and green engineering principles in their operations and have been honored with awards for their efforts.

It is important to note that CSPA represents a broad range of small, medium and large companies and there are various aspects of the regulation that have the potential to have disparate impacts simply on the basis of the size of a company. It is critically important that the regulation does not unfairly impact a company on the basis of whether they have the significant resources necessary to meet the requirements of this regulation.

The consumer products industry develops products that meet or exceed safety requirements of all state and federal agencies in the United States and Canada charged with regulating those products, including the California Department of Pesticide Regulation, the California Air Resources Board, and other state agencies, U.S. Consumer Product Safety Commission (CPSC), the U.S. Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the U.S. Food and Drug Administration (FDA), Health Canada, and Environment Canada.

While there are improvements from previous iterations of this regulation, there remain numerous aspects that make this regulation unworkable in terms of its stated purposes considering the resource limitations of the Department of Toxic Substances Control (DTSC), the public, and industry. To be workable, the regulation must be more flexible to allow for the multiplicity of chemical-product combinations that could be selected, with performance-based instead of laundry-list requirements, with deadlines adjustable to the scope of work. The diversity of chemical-product combinations subject to the rule could include:

- A few products from a few manufacturers to many thousands of products from hundreds of companies;

- Dozens of alternatives already marketed with no known alternatives;
- Chemical use within a category ranging from a very small percentage to 100% of market share;
- Chemical-category sales of a few million to many billions of dollars;
- Relatively simple product technology and performance requirements to extremely complex; and
- A single alternative analysis (AA) by a single consortium to numerous AAs by various companies and consortia representing differing market sectors.

CSPA Concerns

In the following comments on process issues and on specific sections of the regulation, we articulate concerns reflecting our belief that the approach envisioned by the regulation will not achieve the underlying goals and will be overly burdensome to the regulated community, and indeed could impede innovation and inhibit our industry's efforts to maximize the environmental, health and safety benefits of our products. CSPA has identified areas of significant concern which we think must be addressed to make the regulation practical, meaningful and legally defensible for the public, regulated community and the Department

Failure to Comply with Administrative Procedures Act Requirements

CSPA is critically concerned that substantive and fundamental portions of the regulation are not complete nor is the process upon which they will be derived available to ascertain their validity. As noted, the Chemicals of Concern list, the Priority Product Work Plan, including product categories and the Alternatives Analysis guidance are to be published after the rule is finalized. While it is indicated they will be published at a future date, it is unclear if these components will undergo the public review and comment required by the California Administrative Procedures Act (APA) process. The inability to review these crucial documents during the public comment period raises due process concerns and makes it inherently difficult to effectively comment on the July 2012 Proposal and preserve our rights under the APA. This raises a question as to whether the public, CSPA and its members are being deprived of meaningful participation in the regulatory adoption process for the July 2012 Proposal. Moreover, various aspects of the regulatory scheme give rise to the possibility that affected entities will be deprived of property by means of a regulatory adoption process that is wholly inadequate and does not comport with the requirements of the APA.

At a minimum, the Department must ensure that upon release, all documents critical to the implementation of the July 2012 Proposal are subjected to the same rigorous APA process to which the July 2012 Proposal is being subjected.

CEQA Notice of Exemption Not Justified

CSPA is concerned that the Department's application for an exemption from the California Environmental Quality Act (CEQA) is not supported by the stated goals of the Safer Consumer Products Regulation. The Notice of Exemption (NOE) indicates that "With certainty, [there is] no possibility of a significant effect on the environment." Consequently, if the process described in the regulation or any directed regulatory response can be shown to have an effect upon the

environment, the exemption is invalid and the project must complete the CEQA process. In addition, as recognized within the NOE application itself, the Department notes “the need for additional CEQA evaluation will be considered at the appropriate stage of implementation of these regulations,” which indicates that the Department recognizes the need for an Environmental Impact Statement (EIS) while claiming there will be no effect. This line of argument is seriously flawed and countermands the goals and objectives of CEQA. As stated “the regulations are designed to reduce the adverse public health and environmental impacts throughout the life cycle of products through product redesign, or reformulations, manufacturing process redesign, phase-out of harmful chemicals and/or products removal of Chemicals of Concern in products, and other mechanisms,” which clearly indicates the planned benefit of the regulation and the concomitant impact upon the environment. If the result of the process described by the Department with the Safer Consumer Product Regulation and the resulting action as directed by the regulatory response were to work as described, there necessarily would be a reduction in adverse public health and environmental impacts. In the absence of a reduction in adverse impacts, the regulation would be irrelevant and unnecessary. As environmental stewards, it is the Department’s responsibility to show the benefit of the regulation and it clearly does not address the intent of the underlying legislation.

The July 2012 Proposal has the real potential to result in “direct physical change[s] in the environment [and/or] reasonably foreseeable indirect physical change[s] in the environment.”² Therefore, an initial study and programmatic environmental impact report must be completed prior to adoption of the July 2012 Proposal.³ The Department has an obligation to perform an Environmental Impact Report (EIR) and determine any potential effects on the environment and should be discussed with emphasis in proportion to their severity and probability of occurrence. We reviewed the draft Notice of Exemption (NOE) prepared to satisfy the Department’s obligations under CEQA and an NOE is not sufficient to satisfy the Department’s obligations. Specifically, the Department’s belief that the July 2012 Proposal will “eliminate or reduce the adverse public health and environmental impacts of consumer products...” is simply not enough to support its reliance on a CEQA exemption.⁴

CEQA analysis is required to be conducted prior to adoption of the July 2012 Proposal, and should be conducted in a programmatic EIR that analyzes the potential for impacts and potential alternatives to the July 2012 Proposal and/or specific provisions of the July 2012 Proposal that may be feasible and might reduce the potential for significant environmental impacts in connection with its adoption. Preparation of a program environmental document will ensure that the Department considers broad policy alternatives and program-wide mitigation measures at a time when the agency has the greatest ability to deal with cumulative impact problems. A

² See Public Resources Code § 21065; CEQA Guidelines § 15378 (definitions of “Project”).

³ See CEQA Guidelines § 15168; *Plastic Pipe and Fittings Association v. California Building Standards Commission* (2004) 124 Cal. App. 4th 1390, 1413 (“Thus, an activity need not cause an immediate environmental impact to be considered a project”).

⁴ See e.g. *Dunn-Edwards Corp. v. Bay Area Air Quality Management Dist.* (1992) 9 Cal.App.4th 644,656-658 (Categorical exemption is inapplicable where adoption of regulations tightening emission standards for architectural solvents will result in environmental effects.)

programmatic document will also play an important role in establishing a structure within which future reviews and related actions can most effectively be conducted.⁵

There is substantial evidence to support the conclusion that the July 2012 Proposal will cause or compel the use of alternative substances, the impacts of which are unknown and which if history is any guide, can be devastating. As a further and specific example, the potential for environmental impacts associated with end-of-life management requirements contained in § 69506.8 of the July 2012 Proposal, and the anticipated increase in hazardous waste disposal that is likely to result from the same, must be evaluated prior to adoption of the July 2012 Proposal so that the Department can be certain that there are not feasible alternatives to § 69506.8 that would meet the objectives of the Statute and reduce the potential for environmental impacts. Finally, any perceived conflicts between the Statute and existing environmental laws that the Department believes may exempt them from CEQA and which may ultimately be the genesis of environmental impacts of their own, must also be appropriately analyzed and considered prior to adoption of the July 2012 Proposal, if the Department hopes to successfully defend any future CEQA challenge.⁶

At a minimum, the department should complete a CEQA analysis and a programmatic EIR that analyzes the potential for impacts and potential alternatives to the July 2012 Proposal in connection with its adoption.⁷ Preparation of a program environmental document will ensure that the Department considers broad policy alternatives and program-wide mitigation measures at a time when the agency has the greatest ability to deal with cumulative impact problems. A programmatic document also will also play an important role in establishing a structure within which future reviews and related actions most effectively can be conducted.

Completion of Multi-Media Environmental Review

In addition, the Statute includes a separate and specific requirement that a multi-media environmental review be conducted unless it can be conclusively determined that the July 2012 Proposal will not result in environmental impacts.⁸ This requirement is in addition to the requirements of CEQA and is express recognition of the potential that public health and environmental impacts are likely to result from adoption of green chemistry regulation. While the California Environmental Policy Council (CEPC) considered the multimedia environmental review issue in connection with a prior version of the regulation, neither the Department nor the CEPC have analyzed the question of whether multi-media review is required in connection with the July 2012 Proposal. The Statute is clear on this issue, and it is not appropriate to postpone

⁵ See *In re Bay-Delta Programmatic Environmental Impact Report Coordinated Proceedings* (2008) 43 Cal. 4th 1143, 1169.

⁶ See e.g., *Mountain Lion Foundation et al. v. County of Kern Department of Planning and Development Services* (1997) 16 Cal.4th 105, (Delisting the Mojave ground squirrel was a discretionary action that was not properly treated as categorically exempt from CEQA. There was no irreconcilable conflict between CESA and CEQA that exempted the Fish and Game Commission's decision from CEQA's requirements and nothing in the language or history of CEQA or CESA indicated that the Legislature intended delisting to be exempt.)

⁷ See CEQA analyses under submission by Sierra Research and Alston & Bird, LLC.

⁸ Health and Safety Code § 25252.5.

that multimedia review until after the public comment period during the APA process, as it deprives stakeholders of meaningful comment on the proposed rulemaking.

At a minimum, the department should complete a multi-media environmental review of the July 2012 Proposal prior to its adoption.

Inadequate Economic Analysis

CSPA is concerned with the inadequacy of the economic analysis and further requests the Department to embrace the direction Governor Brown implied with his signature on Senate Bill 617⁹ in October, 2011. The bill is intended to create more transparent rulemaking, improve oversight of agencies and encourage policymakers to implement the most cost-effective regulatory option. As noted in the signature message, “Governor Edmund G. Brown Jr. announced today that he has signed the following bills to boost California's economic competitiveness, bring greater fiscal stability to the state and reform the regulatory process to promote business growth:” Given that all regulatory agencies must comply with requirements of the law in just three short months, it is our opinion that the Department should implement the Governor’s direction and complete a more robust economic analysis of this proposed major regulation.

The applicability of the proposed regulation is overly broad. As written, the regulation enables the Department to regulate almost any product for any use. At best, this is potentially redundant with medical device, food and drug, and occupational health and safety rules, but could possibly create conflicts with devices or products that are regulated under other authorities.

Under the proposed regulation, regulatory duplication provisions of the Statute are not considered until the product prioritization section and again at the regulatory response section of the regulation. Further, it gives the Department the discretion to determine the adequacy of the regulatory requirements currently in place as they compare to the breadth of the Safer Consumer Products Regulation’s review. This discretion was not intended by the Legislature, authorized by the Statute under SB 509¹⁰, nor is it necessary. Rather, it is an example of regulatory overreach, suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. This is not a question of the breadth or sufficiency of current regulatory authority and its implementation. Again, the Statute under SB 509¹¹ is clear on the matter, with two applicable provisions:

- (b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.
- (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

⁹ Calderon, http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0601-0650/sb_617_bill_20111006_chaptered.pdf

¹⁰ Simitian, http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/sb_509_GCI.pdf

¹¹ Simitian, http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/sb_509_GCI.pdf; Health & Safety Code §25257.1(b) and (c)

The proposed regulation goes beyond the Statute to assert Department dominance where it believes it would provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were not listed as a Priority Product. It is essential that any applicability of the Safer Consumer Products regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently reviewed. In this regard, regulatory duplication for any product should be an upfront and straightforward question in the applicability stage of the regulation – is the potential health or environmental impact from the chemical in the product reviewed by another regulatory agency or not? Completing the listing, prioritization, analysis and regulatory response of a product and/or chemical that is already regulated is a waste of limited Department resources and fails to meet the practical standard the Department and Director are seeking. Further, where that is the case, by definition any action by the Department would be regulatory duplication, which is prohibited by the Statute.

By failing to provide an economic analysis, it is difficult to assess how our industry would be affected. CSPA thinks the brief review of the potential economic impacts performed by an economist for the California Foundation for Commerce and Education indicates that the impacts on industry could be severe.¹²

At a minimum, the department should suspend this rulemaking until it conducts a full economic analysis as required by Senate Bill 617 (Calderon, Statutes of 2011) and considers alternative regulatory designs and language in light of that analysis.

Concerns about Barrier to Trade

As evidenced by the concerns recently raised in the Technical Barriers to Trade notification filed by the National Center for Standards and Certification Information (NCSCI) and the National Institute of Standards and Technology (NIST) in August¹³, there are concerns that the July 2012 Proposal will affect not only interstate commerce, but world trade, and potentially violate United States international treaty obligations, as they may impose an illegal barrier to trade, as that term is defined by the World Trade Organization (WTO). The Department must consider whether there are revisions that would serve to narrow the scope of the July 2012 Proposal and that would ensure that the July 2012 Proposal is not ultimately deemed an illegal barrier to trade.

§ 69501 Purpose and Applicability

CSPA is concerned language proscribing regulatory duplication present in the October 2011 Informal Draft has been removed. The deleted language was consistent with the goals of the regulation and CSPA recommends that the following language be inserted into § 69501: Purpose and Applicability:

(4)(A) This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s),

¹²Change, Andrew, "The Consumer Impact of California's Green Chemistry Initiative", California Foundation for Commerce & Education, October 8, 2012.

¹³ <http://tbtims.wto.org/web/pages/edition/notification/Regular.aspx?ID=305362>

and/or applicable international trade agreements with the force of domestic law, that, in combination:

1. Address the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and
2. Provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product.

(B) The Department may re-evaluate a determination previously made pursuant to this paragraph and rescind the determination if the Department finds that the facts and/or assumptions upon which the determination was based were not, or are no longer, valid.

§ 69501.1 Definitions

CSPA recommends that the Department harmonize definitions with existing international and national definitions used in other chemical and product regulations (e.g., OECD, EPA, GHS, TSCA) to promote clarity. The use of a non-harmonized definition leads to great uncertainty and to infinite variations and impracticality.

In general, it is difficult to consider the promulgated Chapter 54 Hazard Traits in conjunction with the current regulation. In some cases, the current regulation further defines definitions and the inconsistencies between the two will inherently lead to confusion. For example, Health and Safety Code § 69501.1(a)(17) defines “bioaccumulation” to be broader than the definition found in § 69405.2, or § 69501.1(a)(4) defines “adverse ecological impacts” and refers to Article 4 of Chapter 54, which is entitled “Adverse Environmental Impacts”. CSPA recommends that the Department coordinate with OEHHA on these issues to ensure that definitions and standards are consistent and work in concert with the Statute’s prioritization mandate.

A number of the definitions refer to quantitative thresholds without providing any means of comparison for determination of thresholds. Accordingly, Appendix G to the CEQA Guidelines provides direction on the means to establishing quantitative thresholds that would be appropriate in the green chemistry context. For example, pursuant to Appendix G, Section III., item (b), a project that violates stationary source air quality standards or contributes to existing or projected air quality violations will be determined to have a potentially significant air quality impact under CEQA. The means to determining whether the aforementioned violations will occur is quantifying baseline emissions in the project vicinity and comparing the baseline and project emissions to ambient air quality standards. No doubt, there are quantitative standards applicable to emissions of Nitrogen Oxides, Particulate Matter, Sulfur Oxides and other criteria pollutants intended to be covered by the definition of “adverse air quality impacts.” In the event baseline plus project emissions exceed those quantitative standards, a potentially significant impact conclusion is reached unless: (1) the project is modified to eliminate the exceedance; or (2) mitigation intended to address the exceedance is imposed. In the greenhouse gas context, rules, regulations and guidance like EPA’s tailoring rule, South Coast Air Quality Management District’s Interim Guidance and Delaware and New York regulations applicable to hydrocarbon emissions, provide clarity about the levels of greenhouse gas emissions that implicate a potentially significant impact. Again, the existence of transparent, quantifiable thresholds gives

project proponents a clear understanding of what constitutes a significant or adverse impact, and encourages design that will minimize or eliminate the same.

CSPA is concerned about the lack of clarity with the definition of “adverse” and its subsequent use in “adverse air quality impacts”, “adverse ecological impacts”, “adverse water quality impacts”, and “adverse waste and end-of-life impacts.” The definitions must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and Alternatives Analysis process, and so that the process for selecting Priority Products is appropriately transparent.

CSPA is concerned about the lack of clarity with the definition of “indirect” and what it encompasses. How does one measure that? That same definition further identifies “changes in population size” as a relevant endpoint but refers to a change in a period of time. These definitions must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and Alternatives Analysis process, and so that the process for selecting Priority Products is appropriately transparent.

How is the baseline determined to ascertain whether there's been an increase or decrease? What metric is being used? Has this metric or baseline been shared with and agreed upon by stakeholders and regulators? The definition must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and Alternatives Analysis process, and so that the process for selecting Priority Products is appropriately transparent.

CSPA is concerned about the elimination of “assembled product” which now appears to be identified as the new term “homogeneous material”.

(34) “Homogeneous material” means either of the following:

(A) One material of uniform composition throughout; or

(B) A material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, or abrasive processes.

It comes into play as potentially being the focus of an AA by being defined as a "product" which means, among other things:

"A component, or a homogeneous material within a component, that is identified, under § 69503.4(a)(2)(B), as the minimum required focus of an AA."

It is not clear why this is needed – “component” should satisfy all needs for the focus of an Alternatives Analysis. CSPA recommends removal of this definition.

The definition for “reliable information” is an overly broad definition and no methodology for evaluating said information is given (i.e., weight of evidence). The Initial Statement of Reasons (ISOR) explains (page 33-35) in great detail the different types of information and the relative quality of various types of reports and research. But other than indicating that scientific studies will be evaluated on a case-by-case basis, there is no indication of how the information will be

evaluated, especially given the broad scope of types of studies and the need for sufficient expertise in their evaluation and comparison.

The addition of “workers” as a potentially sensitive subpopulation appears to duplicate the existing authority of Cal/OSHA to protect workers from unreasonable exposures to chemicals. California State Plan, Section 19 OSHA (1970), approved May 1, 1973, and certified August 19, 1977. Per the agreement between the State of California and OSHA, the state plan “applies to all public and private sector places of employment in the state, with the exception of Federal employees, the United States Postal Service, private sector employers of Native American lands, maritime activities on the navigable waterways of the US, private contractors working on land designated as exclusive Federal jurisdiction, and employers that require Federal security clearances.”¹⁴ CSPA recommends removal or revising the definition to clearly address the duplicative authority.

For assembled products, CSPA recommends that “inaccessible components” be clearly defined and removed from prioritization. In § 25252(a), the Department is directed to consider potential exposure and exposure pathways, which supports the exclusion of inaccessible components from coverage by the regulation. In addition, the Department has already established the “highly durable” product category that is treated differently under the regulations because of inaccessibility or lack of exposure to a priority chemical. This category is similar to the “inaccessible components” concept. In both cases, there is an assumption that exposure will be low during the useful life of the product.

CSPA is concerned with the definition of “Trade Secret” and CSPA recommends removal of “Trade Secret” definition entirely and refers the Department its comments on § 69510 Trade Secret.

§ 69501.2(2) Duty to Comply and Consequences of Non-Compliance

CSPA emphasizes that the process of forming a consortium is necessarily time-consuming and must address a variety of issues including anti-trust, trade secret, data sharing, cost sharing and intellectual property. There can be great benefits to such programs to drive innovation on common problems; however, there are potential anti-trust concerns with organizing such a group to accomplish the objectives of this regulation as envisioned by the Department. For example, the July 2012 Proposal encourages consortia to work together in developing a single Alternatives Analysis for an entire product line, and/or cooperate in an end-of-life management program, the anticompetitive effects of which could result in the Department selecting single source replacement for an entire industry. Both of these two examples might compel activities that violate antitrust laws, lead to commoditization of goods, and stifle innovation results in competitive markets. That being said, CSPA and our member companies are keenly aware of antitrust requirements, and cannot compromise compliance with antitrust laws.

¹⁴ See also, 29 CFR 1952.172.

At a minimum, CSPA encourage the Department to explore how it might revise the July 2012 Proposal to address these concerns and potential conflicts that may arise under the July 2012 Proposal.

§ 69501.3(b) Information Submission and Retention Requirements

CSPA agrees with benefits of the usage of an electronic format, but it is also critical that the specifics of the required submission format be provided as soon as possible. CSPA recommends that the Department adopt an internationally recognized format, such as The International Uniform Chemical Information Database (IUCLID).

In addition, CSPA questions the requirement that most relevant submissions be signed and certified under oath by the owner or officer of the company, or their authorized representative and by the individual responsible for preparing or overseeing the preparation of the documentation or information. Only the person preparing the relevant document should need to verify the accuracy of the document they prepared. It is not necessary for senior management to review every notification sent to the Department, particularly the proliferation of notifications that this proposed regulation contemplates. The requirement for owner and operator involvement and to require two sets of signatures is over-reaching and impractical. It creates an administrative burden that will not further the accuracy of the documents filed with the Department since the person with most knowledge is already required to sign and provides no apparent benefit.

§ 69501.4(a)(4) Chemical and Product Information

CSPA is concerned with the lack of clarity about the type or how much new information can be requested to be generated at the request of the Department. As written, there are no limits specified in the regulation as to the scope and breadth of new information that can be requested. This presents an undue burden upon companies to generate information without any requirement for the Department to justify the benefit of the information. There is also the possibility for unequal treatment of companies if they do not have the capability to generate the requested information. It is also unclear how confidential business information and trade secret information will be protected.

At a minimum, CSPA recommends that the Department publish a clear justification and benefit for a responsible entity generating new information.

§ 69501.4(d) Safer Consumer Products Partner Recognition List

CSPA questions the benefit of recognition on the Safer Consumer Products Partner Recognition List. CSPA is also concerned the posting of information about the Alternative Analysis of product that is not a Priority Product would imply that an Alternative Analysis or reformulation by others should be completed. In addition, will a voluntary Alternative Analysis undergo public comment and/or peer review to the same level of rigor as mandated Alternative Analyses? It would be egregious to recognize a voluntary alternative analysis process that had not been held to the same level of review and rigor of the formal process described in this regulation. CSPA recommends that a voluntary alternative analysis include scientific peer review and a public comment period to prevent abuse.

§ 69501.5 Availability of Information on the Department's Website

CSPA is concerned with the lack of clarity and benefit of this activity while the costs associated with maintaining information are undefined and potentially burdensome to the agency or misleading to the public and/or stakeholders if not readily maintained.

CSPA recommends that the Department clarify these issues and ensure that this activity is warranted.

§ 69501.5(b)(3)(D)

CSPA questions the rationale, legality and benefit of posting the identity of the person identified as responsible for fulfilling the requirements of article 5. CSPA urges removal of this provision.

§ 69502.2 Chemicals of Concern Identification

CSPA has significant concerns associated with the process of listing Chemical of Concerns, which is particularly troubling in that the Department and the Green Ribbon Science Panel (GRSP) expended significant resources attempting to address stakeholder concerns and to maintain transparency in the process. Consider the passage:

“DTSC recognizes that before decisions are made final, stakeholders need to examine the rationale, data, and information sources that led DTSC to the decisions made. Transparency and stakeholder input (public comment period and a workshop) are built into Articles 2 and 3 by requiring DTSC to provide its rationale for proposing to remove or add additional Chemicals of Concern and Priority Products. To address stakeholders' concerns about the lack of predictability in listing Chemicals of Concern, the regulations establish an initial list of Chemicals of Concern (~1,200 chemicals) that are based on the work already done by other authoritative organizations. An informational list will be posted on DTSC's website within 30 days of the effective date of the regulations. However, a person does not need to wait for the publication of the informational list since the chemical lists are identified in regulations.” (ISOR, pages 54-55).

A critical component of transparency is the ability to replicate the efforts of others to validate and assess the predictability of the process. Efforts on our part to replicate the initial list of Chemicals of Concern (~1,200 chemicals) using the lists provided generated much larger lists of chemicals. In fact, the previous version of the regulation used the same set of lists to generate initial list of Chemicals of Concern and resulted in ~3000 chemicals.¹⁵

While it appears there is a process by which the Department narrows the scope of the work of the authoritative organizations to limit the list, it is not clear in the regulation. Additionally, referring to the underlying chemical lists is disingenuous and ignores the reality that each list was created for a purpose vastly different than the scope of the current regulation. Considering these factors, it is inherently difficult, if not impossible to comment on the Chemical of Concern

¹⁵ See the page 2 of the Summary of the October 31, 2011 Informal Draft - <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf>.

identification process in the absence of an actual result of the identification process. CSPA also reiterates our request that upon release of a Chemical of Concern list, all documents critical to the implementation of the July 2012 Proposal are subjected to the same rigorous APA process to which the July 2012 Proposal is being subjected.

That being said, a variety of source lists is appropriate and will be useful as a starting point in a true prioritization process. CSPA appreciates the Department's efforts to modify the previous draft of source lists to better represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment. There are several remaining concerns:

- (1)(C) "European Commission DG ENV, towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption" is inappropriate. This should be removed since the objective in creating the candidate list was to identify chemicals that deserved further investigation on whether they were endocrine disruptors, not to determine if a particular chemical had the endocrine toxicity hazard trait.
- (1)(H) "Chemicals that are identified as Persistent, Bioaccumulative, and Inherently Toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List" should be updated to reflect the most up-to-date information.
- (1)(I) IARC's Carcinogen list should not include 2B substances, as the evidence level is less than that of other international carcinogen sources.
- (1)(L) Office of Health Assessment and Translation reproductive and developmental toxicants. CSPA agrees with utilizing this list, but notes that chemicals should be limited to those identified as Serious Concern and Concern.
- (2)(F) California Biomonitoring program, where numerous chemicals have been listed, some of which are beyond those tested in the CDC Biomonitoring program. The California program is in the early stages, and little testing has been completed and validated. Chemicals that are not included in CDC's studies and which have not yet been studied in California's program should be considered to have "exposure information" under this regulation.
- (2)(H) OSPAR list of substances for priority action is inappropriate. This should be removed as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input.

CSPA questions how inconsistencies between underlying lists used for the generation of the Chemicals of Concern are addressed and treated in the proposed Regulation. IRIS and IARC define carcinogenicity differently (Table 1), especially with respect to their treatment of evidence of carcinogenicity in animals. There are numerous chemicals that meet the criteria on one list, but do not meet the criteria on another list. For example, Aniline (CAS RN 62-53-3) is considered a B2 carcinogen under the 1986 IRIS Guidelines, but is an IARC Group 3 (Not classifiable as to its carcinogenicity to humans). Is it unclear which list would be given precedence and why. CSPA requests clarification and revision.

CSPA recommends that the Department develop a methodology to clearly articulate these decision points to ensure that the process is scientifically defensible.

Table 1: Comparison of IRIS and IARC Cancer Grouping

IRIS	
A	Human carcinogen
B1	Probable human carcinogen - based on limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in animals
B2	Probable human carcinogen - based on sufficient evidence of carcinogenicity in animals
C	Possible human carcinogen
	Carcinogenic to humans
	Likely to be carcinogenic to humans
IARC	
Group 1	Carcinogenic to humans
Group 2A	Probably carcinogenic to humans
Group 2B	Possibly carcinogenic to humans

In addition, CSPA is concerned about how inconsistencies between the various Proposition 65 listing mechanisms of chemicals will be considered. The listing methods and underlying scientific rigor vary greatly. For example, the state qualified experts listing mechanism involves significant scientific discussion and public comment, while the Labor Code listing mechanism is administrative and explicitly excludes consideration of scientific evidence.

CSPA recommends that the Department limit listing to chemicals that undergo a scientifically defensible determination.

§ 69502.2 Chemicals of Concern Identification

CSPA is very concerned about the process that is being used to narrow down the list of Chemicals of Concerns. The ISOR, summary documents and press releases indicate there are approximately 1200, further filtered to 185 Chemicals of Concern in the latest release, but lists used are identical to previous drafts (which indicated the number of Chemicals of Concern was approximately 3000). Efforts to replicate the Chemical of Concern list results in considerably more than 3000 Chemicals of Concern. The process information is critical to instill confidence in the process and should be peer reviewed and be open to public review and comment.

CSPA is also concerned that some chemicals on the underlying lists are not identified by Chemical Abstract Service Registry Number (CAS RN) or other clear identification, and strongly recommends that any generated lists include clear identification of all listed chemicals to ensure that it is clear to the regulated community which chemicals are affected and who needs to comply.

§ 69502.2(b)(2) Exposures

CSPA is concerned the described proxies for exposure only consider potential presence and do not take into account risk-based determinations or potential for adverse impacts or harm.

CSPA encourages the Department to utilize use information in conjunction with exposure information to aid in risk-based determinations of potential adverse impacts.

§ 69502.2(b)(3) Availability of Information

CSPA agrees that a greater amount of reliable information should improve the robustness of decision making, but reliable information substantiating the lack of potential exposure or adverse impacts should also be considered.

§ 69502.2(b)(4) Safer Alternatives

CSPA advises that identification of a “safer alternative” in another product without going through a detailed analysis of the functions and requirements of a chemical in the product is not advisable and is a pathway fraught with regrettable substitutions.

§ 69502.3 Chemicals of Concern List

CSPA is very concerned that in the absence of a reproducible Chemicals of Concern list generation process, 45 days is insufficient time to adequately review the Chemicals of Concern list. Moreover, there is no indication of what actions can or will be taken upon completion of the comment period. For example, can Chemicals of Concern be added or deleted based upon comments from stakeholders? What types of information or comments would lead to a removal or addition of a Chemical of Concern? In addition, while the regulation specifically calls for a public review and comment period for revisions, it is not clear that the initial list will be posted for review and comment.

CSPA suggests revising § 69502.3(c) to read: “The Department shall make the initial and any proposed revisions to the Chemicals of Concern list available on its website for public review and comment” to address this concern.

§ 69503 General

CSPA is critically concerned that the scope of product categories be limited to products with similar intended uses, similar targeted customer bases and function of the Chemical of Concern in the Priority Product. Therefore, it is sensible for the product category to be identified by the Global Product Classification (GPC) Standards specified to the Brick level. If the product category is too broad, it will make an Alternative Analysis extremely difficult, excessively complex or meaningless and will likely encompass an unmanageable number of responsible entities. At present, the scope and breadth of the product categories does not provide sufficient specificity nor is there any description for the process for determination of the product categories within the regulation. As noted in the ISOR, the Priority Product Work Plan is “intended to provide a level of certainty and predictability to responsible entities and other stakeholders regarding the types of products that will be considered for evaluation prior to releasing a proposed Priority Product List.”¹⁶ CSPA is very concerned that the utilization of the GPC Family (a broad division of a segment) or GPC Class (a group of like categories) would result in an unmanageable size and number of impacted entities.

CSPA recommends the utilization of the GPC Brick level, which defines categories of like products to provide a readily identifiable and manageable size of impacted entities. In addition,

¹⁶ Initial Statement of Reasons Safer Consumer Products, Page 99.

we reiterate that upon release of a product category list, that all documents critical to the implementation of the July 2012 Proposal are subjected to the same rigorous APA process to which the July 2012 Proposal is being subjected.

§ 69503.2 Priority Products Prioritization Factors

CSPA supports the inclusion of the prioritization factor of “to contribute to or cause adverse public health and/or environmental impacts, considering reliable information relevant” (§ 69503.2(a)(1)(A)) to harmonize the language with other California regulations.

CSPA recommends that the Department ensure that regulatory duplication concerns have been considered and addressed prior to any prioritization of Products.

CSPA is concerned about the lack of clarity with the definition of “widespread adverse public health and/or environmental impacts”. What is intended by the usage of “widespread” in this context? In addition, market presence information may provide additional information about potential exposure, but should be provided with additional detailed information (fate, degradation, environmental monitoring, etc.) as a potential exposure is not always an actual exposure. It should also be noted that market leaders will be identified as having the greatest exposure, fairly or unfairly. There is also the possibility that an entity that dutifully provides market information is more likely to be impacted providing an incentive to entities to ignore the submission of market information. In addition, the regulation has expressed special consideration for certain contributors under § 69503.2(a)(1)(A)2.a-d); will this section also take into account issues related to environmental justice or conflict minerals?

CSPA recommends that the Department clarify these issues and subject the revision to further public comment.

§ 69503.2(b) Key Prioritization Factors

CSPA is concerned with the lack of clarity concerning “significant ability” factor included in the prioritization factors. While the corresponding section in the ISOR goes into detail on the factors that may be considered “significant”, there is no description for how this determination will be made.¹⁷

CSPA recommends defining thresholds or a process to clarify the “significant ability” factor definition.

§ 69503.3 Process to Evaluate Products Using the Prioritization Factors

CSPA is very concerned that additions to Chemicals of Concern list via Executive Order or Petition process circumvents the public comment and review process.

CSPA recommends that this provision be removed to ensure confidence, transparency and defensibility of the scientific process.

¹⁷ Initial Statement of Reasons Safer Consumer Products, Page 96-97.

§ 69503.3(g) Initial Priority Products Lists(s)

CSPA is concerned this section is unclear and appears to contradict the “Changes” document, which is described as limiting chemical selection to seven hazard traits and from the chemical listed on one of 22 lists. The process being used to narrow the list of chemicals is unclear.

CSPA recommends that the Department publish the process guidance and subject the revision to further public comment to ensure scientific defensibility.

§ 69503.4(a)(2)B.4a Priority Products List

CSPA is concerned the definition for products designed or intended for children is overly broad and unique and recommends that the definition be harmonized with the Consumer Product Safety Improvement Act (CPSIA) definition and guidance available at <http://www.cpsc.gov/businfo/frnotices/fr10/childproduct.pdf>.

§ 69503.4(a)(2)B.4

CSPA is concerned about the lack of clarity for the exclusion from highly durable products that are “intended to be worn or placed on the human body, dispersed as an aerosol or vapor, or applied to hard surfaces with the likelihood of runoff or volatilization.” CSPA recommends removal of this sentence or revision to address the lack of clarity.

CSPA recommends that when the Department publishes the Priority Products List responsible entities should have the following options:

- Provide reasonable evidence the Priority Product does not contain the Chemical of Concern above the Alternatives Analysis threshold.
- Provide reasonable evidence the Priority Product does not result in human exposure or environmental release of the Chemical of Concern due to product design and handling (e.g., use of lead in sealed storage batteries, where system exists to assure appropriate recovery/recycling.)
- Provide notice the Priority Product containing the Chemical of Concern will be withdrawn from the stream of commerce in California.
- Provide notice that a responsible entity will engage in an Alternatives Analysis to assess alternatives for a Chemical of Concern in the Priority Product, either through a consortium or an individual, without specification of how Alternatives Analysis will be produced.
- Request an extension to determine whether the Priority Product contains a Chemical of Concern above the Alternatives Analysis threshold when the Chemical(s) of Concern causing the product prioritization are known contaminants of other raw materials or components.

CSPA is critically concerned that sixty days is not adequate to determine whether one or more consortia will be formed and whether a company will join one.

CSPA requests the Department extend the current 60 day timeframe to 45 days for an initial acknowledgement and up to an additional 180 days to allow for determination of path forward

and/or consortia formation. CSPA also requests that a provision for reasonable, justifiable extensions be added.

§ 69503.5 Alternatives Analysis Threshold Exemption

CSPA is concerned about the Alternatives Analysis Threshold Exemption provision. If a product contains a Chemical of Concern which is below the alternative assessment threshold, notification to the department of such should not be required. The point of the threshold is to specify a level above which action should be required and conversely, below which no action is required. An exemption notification requirement will detract resources from the task at hand, reducing chemicals of concern, and is also counterproductive. Companies who are actively managing chemicals in their products will seek to comply with the massive paperwork exercise that this requirement will become. Trying to account for trace levels of chemicals, which are acknowledged by the Department as not being a priority because they are below the alternative analysis threshold set by the Department, serves no purpose and will create a burden for responsible companies. Again, with this provision, the Department is redirecting the energies and monies of industry from the important goals of the Statute to administrative paperwork tasks.

In addition, usage of the minimum detectable concentration is inappropriate in most case, is inconsistent with other regulatory approaches and imparts a significant and unwarranted analytical burden. The fact that analytical chemistry continues to advance the ability to detect compounds at lower and lower levels is no rational basis to require an AA.

CSPA recommends that the Department establish an Alternatives Analysis Threshold initially at 0.1% and adjust by factors related to public health and/or the environment (c(3)) rather than analytical method based limits of detection (c(2)).

§ 69503.6(a)(6) Alternatives Analysis Threshold Exemption Notifications

CSPA is critically concerned about the Alternatives Analysis Threshold Exemption process. If an Alternatives Analysis Threshold Exemption Notification is to be required, the Department should first remove the implication at § 69503.6 (a)(5) and (a)(6) that only analytical testing results are appropriate substantiation that a product meets the Threshold Exemption standard. Manufacturers commonly rely on supplier certifications regarding purchased material content to understand product ingredients and impurities, and do not routinely test all purchased materials or finished goods. Given the sheer number of “chemicals of concern” based on regulations and customer restricted/banned substances lists, testing for all these is cost-prohibitive. Responsible manufacturers augment supplier information with testing when knowledge of the chemistry of the product indicates probable presence of chemicals of interest, or when there is cause to doubt the veracity of the supplier certification. But to require all products containing the Chemicals of Concern below the Alternatives Analysis threshold to be tested is a waste of resources when knowledge of suppliers, product formulation or construction, expected chemistry, and supplier certifications would provide a high degree of assurance that the Chemicals of Concern are below the Threshold Exemption level.

This approach is not only standard manufacturer practice but is also recommended in the European Union (EU) for compliance with the Restriction of Hazardous Substances (RoHS)

Directive (on the restriction of the use of certain hazardous substances in electrical and electronic equipment). The EU RoHS Directive was a first-of-its-kind approach to controlling the use of certain chemicals of concern, with a very broad scope of household, commercial, professional and industrial products.¹⁸ Manufacturers are advised to “consider the role that both materials declarations and component or material analysis [i.e., analytical testing] could play.” The Notes explicitly say that testing “**may** [emphasis added] be undertaken either to verify supplier declarations or to establish the presence or otherwise of the restricted substances in those cases where no declaration is available. It may also be undertaken if there are doubts over the reliability of declarations.”

The RoHS Guidance Notes also provide rigor to this compliance process by use of a detailed flowchart in Annex D (p. 35). First, components and materials should be reviewed for the risk of restricted substances being present. Secondly, suppliers should be formally classified as to their understanding of the requirements of the directive, the strength of their compliance management systems, their own program for testing of high risk (i.e., risk of the restricted substance being present) materials, and their classification of their suppliers.

This twin approach of supplier assessment and material assessment, augmented where needed with testing, is accepted in the EU, and should be acceptable for California's Safer Consumer Products Regulation.

Consider also the real world consequences of requiring testing as the only substantiation for the Alternatives Analysis Threshold Exemption Notification. Say a manufacturer has a priority product that contains a carcinogen Chemical of Concern that was the basis for the product being listed as a priority product, but the Chemical of Concern is below the Threshold Exemption. Given that § 69503.5 (b) defines the threshold exemption as a cumulative percentage (all Chemicals of Concern that exhibit the same hazard traits and/or same environmental or toxicological endpoints), there would need to be testing for not only the carcinogen Chemical of Concern that was the basis for the product being listed as a priority product, but also any other DTSC-defined carcinogen. Taking into account only Proposition 65, IARC, NTP and IRIS (not a complete list of DTSC-defined carcinogens), that would amount to testing for over 550 unique CAS numbers, plus an untold number of CAS numbers that are on these lists by virtue of being a member of a listed chemical category.

There are a number of factors that go into determining an estimate for the required testing costs for one Chemical of Concern, including:

- Does an analytical method exist for Chemical of Concern that is appropriate for the Priority Product?
- Is the Chemical of Concern intentionally added or unintentionally added?
- Does the supplier test for the Chemical of Concern?
- Are there resources in-house that can perform the testing?

¹⁸ The UK Department for Business Innovation and Skills (BIS) RoHS Guidance Notes explains how manufacturers should approach their compliance obligations, and can be found at: <http://www.bis.gov.uk/assets/biscore/business-sectors/docs/r/11-526-rohs-regulations-government-guidance-notes.pdf> See especially points 33, 36, 37 and 38 on p. 11 of the RoHS Guidance Notes.

The analytical method development and testing costs alone for a single Chemical of Concern could easily be greater than \$20,000, while the additional business costs within a company would easily exceed \$50,000 depending upon whether a company has the internal resources or if it must seek outside consultation.

Thus, the regulations at § 69503.6 (a)(5) and (a)(6) should be revised to make it explicitly clear that the Alternatives Analysis Threshold Exemption Notification requires a manufacturer to substantiate its belief that the Chemicals of Concern are below the Alternative Analysis Threshold Exemption, but that this substantiation may take a number of forms, including but not requiring test data.

§ 69503.6(c)

CSPA is concerned about the lack of clarity in the definition of “significantly changed” in the requirement to submit a revised Exemption Notification.

The definition must be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and Alternatives Analysis process, and so that the process for selecting Priority Products is appropriately transparent.

§ 69503.7 Priority Product Notifications

CSPA is concerned about the lack of clarity of when a responsible entity is required to submit an Alternatives Analysis Threshold Exemption Notification. The ISOR indicates that, “If a product does not contain a Chemical of Concern, it is not subject to this notification. Only responsible entities for Priority Products that contain the Chemical of Concern that is the basis for its listing are required to submit an Alternatives Analysis Threshold Exemption Notification if they wish to be exempt from the Alternatives Analysis.”¹⁹ However, it is not clear in the regulations that this is the case. This very important point, that manufacturers of Priority Products that do not contain a Chemical of Concern are not required to submit an Alternatives Analysis Threshold Exemption Notification, should be in the regulatory text, and not merely in the ISOR.

CSPA recommends that the Department elevate this concern to the regulation, clarify the issues raised and subject the revision to further public comment.

Article 4. Petition Process for Identification and Prioritization of Chemicals and Products

CSPA is concerned that the Petition Process does not explicitly include an opportunity for public comment and scientific review of the merits of the petition. CSPA recommends that a public comment provision be added to § 69504.1 that is similar to § 69502.3(c).

(c) The Department shall make petitions available on its website for public review and comment during the Merit Review process, along with supporting documentation, including the petitioner's rationale and a bibliography of the supporting information and information sources, prior to making a decision on the whether to grant or deny the

¹⁹ Initial Statement of Reasons Safer Consumer Products, Page 111.

petition. The Department shall hold one or more public workshop(s) to provide an opportunity for oral comment on the proposed petition. The Department shall send to individuals on the electronic mailing list(s) that the Department establishes related to this chapter, and post on its website, a notice regarding the petition and supporting documentation. The notice must include all of the following:

- (1) The last day for the public to submit written comments on the petition. The last day for submission of public comments shall be no sooner than forty-five (45) days from the date the availability of the petition is sent to individuals on the electronic mailing list(s) that the Department establishes related to this chapter, and posted on the Department's website;
- (2) The method(s) for submitting comments to the Department; and
- (3) The date, time, and location of the public workshop(s).
- (d) The Department shall make a determination to grant or deny the petition after review of public comments. The Department may respond to some or all public comments received.

§ 69504(b) Applicability and Petition Contents

CSPA is concerned about the delisting/petition process related to a Chemical of Concern listing which is based upon multiple lists that are based upon a single list (i.e., Prop 65 based upon IARC 2B). Would removal from one list require delisting or would the Department require that the Chemical of Concern be delisted from all applicable lists? This certainly opens the possibility that a Chemical of Concern could no longer be formally listed but the responsible entity has no recourse within the regulation.

At a minimum, the Department must ensure that upon release, all documents critical to the implementation of the July 2012 Proposal are subjected to the same rigorous APA process of which the July 2012 Proposal is being subjected.

§ 69505 Guidance Materials

CSPA is concerned that the length of time for the Alternatives Analysis process is insufficient. Additionally, the process only allows a responsible entity one extension. Those conducting an Alternatives Analysis may need additional extensions to adequately seek and consider safer alternatives. For example, an applicant engaged in the US EPA Pre-Manufacture Notification (PMN) process is at the mercy of the regulatory agency in terms of approval. The PMN process typically takes up to 90 days for agency review but can take longer if additional data is requested. Another scenario to consider, which may end in the necessity of additional time to complete the Alternatives Analysis process, is: If two responsible entities are working on the "same" safer alternative and the second applies for patent protection the first entity will not be able to continue the Alternative Analysis for the alternative and would need to seek other alternatives and thus would need additional time to complete the Alternatives Analysis. There is also concern that if the Alternatives Analysis timeframe is overly restrictive, it increases the likelihood for regrettable substitutions.

CSPA requests additional flexibility in the timeframe provided for the Alternatives Analysis process: 180 days to file the Preliminary Alternatives Analysis Report (i.e., four months after

notification of a Priority Product Listing) is only feasible if there is a quick decision to complete the Alternatives Analysis as an individual and not as part of a consortium. In most cases, responsible entities will determine whether a consortium is forming and whether participation is appropriate. Formation of consortia could take up to six months, depending on the number of responsible entities and Priority Product/Chemical of Concern.

After a consortium is formed, four months to submit the Preliminary Alternatives Analysis Report is still difficult depending on the Priority Product/Chemical of Concern. By way of explanation, administrative steps in the initial stages of the formation of consortia include issuance of a Request for Proposal (RFP) and selection of consultants, which can take months to initiate and formalize.

CSPA encourages the Department to carefully consider the burden and lessons learned from the EPA Design for the Environment Alternatives Assessment of BPA in Thermal Paper and apply the lessons learned. <http://www.epa.gov/dfepubs/projects/bpa/about.htm>

CSPA requests the Department allow responsible entities to file for extensions 15 and 30 days before deadlines for Preliminary and Final Alternatives Analysis Reports, respectively to allow for adequate and timely filings.

§ 69505.1(c)(1) Alternatives Analysis: General Provisions

CSPA is critically concerned about the costs, technical requirements and confidentiality issues associated with certified assessors. There is a lack of clarity regarding the role of the certified assessor and whether the certified assessor is in the employment of the responsible entity, consortium or the Department. There are appreciable concerns about the protection of intellectual property and confidential business information belonging to the responsible entity if the certified assessor is not under their employment or appropriate legal protection. It is recommended that the certified assessor be in the employment or contractually bound to the responsible entity/consortium. There is also a lack of clarity to the timing and involvement of the certified assessor with respect to the Alternatives Analysis process, in particular with the timeframe of two years from the effective date of the regulations. For the first Priority Product Alternatives Analysis, the Alternative Analysis may not be concluded within two years.

CSPA requests an amendment to provide that Alternative Analyses submitted for the first round of Priority Products are not required to be completed by a certified assessor. We also recommend that the Department defer provisions requiring certified assessors until such time as programs can be established and adequate numbers of assessors can be certified.

69505.1(e) Certified Assessors

CSPA has significant concerns about the role and qualifications of the certified assessor as set forth in the proposed regulation. The regulation indicates that “each Alternatives Analysis completed on and after the date that is two years after the effective date of these regulations shall be performed by, or under the responsible charge of, one or more assessor(s) certified under Article 8 for the appropriate product type or industry sector.”

As set forth in, Article 8 “Accreditation Bodies and Certified Assessors,” of the proposed regulation, DTSC is under the erroneous notion that mere academic training can provide adequate knowledge for a person to be able to either conduct or lead a robust alternative assessment. Two years professional experience is not enough to be fully aware of the intricacies of formulating consumer products and post-graduate work in the performance of Alternatives Analyses just cannot substitute for the two years of professional experience. Significant experience in the laboratory is typically required for a formulator to know how to develop formulations that are stable and safe for several years, provide the benefits expected by consumers at a cost that they can afford, and then apply that to new ingredients. Five to ten years of experience working as a formulator or processing engineer in a company making consumer products should be the minimum experience required, along with significant experience and training in project management. Global companies may also not have the correct academic and accreditation requirements as required by the regulation; global companies will likely have to rely on global formulation teams based outside the United States. As such, the final regulation will need to have the requisite flexibility to accept the qualifications of certified assessors from around the globe.

The proposed Article 8 assessor training and certification programs are also far too ambitious. To successfully develop a product for the consumer market requires the melding of many different skills, including chemistry, chemical engineering, packaging engineering, microbiology, toxicology, environmental toxicology, manufacturing, quality, occupational safety, finance, consumer insight (psychology, for example), marketing and more. The requirement that one person, especially one with so little real experience in formulation chemistry, to show expertise in all these fields is just not possible. A company may have experts in their respective fields and have many years experience and knowledge in that field, but not in other facets of formulation. Developing and bringing a safe and successful product to market is the result of the combined efforts of these experts plus years of experience in making it all come together.

If a certified assessor is hired by a company to conduct the Alternatives Analysis that company also has to ensure that the assessor is bound by strict confidentiality requirements. The assessor will not only have to obtain confidential information about formulations but also the manufacturing and supply chain capability of the company to do the job adequately.

CSPA recommends that the role of certified assessor be eliminated in favor of developing a list of guidelines, or checkpoints, that need to be addressed when conducting an Alternatives Analysis. When DTSC receives the formal Alternatives Analysis reports, it can quickly ascertain whether the appropriate factors have been evaluated. Any training that is to be done should be given to DTSC staff who review the Alternatives Analysis reports.

§ 69505.3(a) Alternatives Analysis: First Stage

There is an ambiguity throughout the regulation when the term “Chemical(s) of Concern” is used. This section begins by saying that references in this section to “Chemical(s) of Concern” mean the chemical that is the basis for the Priority Product being listed. But it is unclear in other sections, especially in the Regulatory Response section, whether Chemical(s) of Concern means

the basis Chemical(s) of Concern or chemicals on the large Chemical(s) of Concern list. A new term should be introduced, e.g., “Basis Chemical(s) of Concern,” and used whenever the regulation refers to the chemical that is the basis for the Priority Product being listed. Otherwise, “Chemical(s) of Concern” could be interpreted to mean the full Chemical(s) of Concern list.

While subsection (b)(3) allows the responsible entity to eliminate alternatives during this initial screening phase, it does not allow eliminating alternatives based upon economic, consumer acceptance or performance considerations. These are important factors in choosing an alternative and without having them as a screen; the Alternatives Analysis could become a fictional creative writing exercise leading to no actually implementable regulatory responses. Additionally, subsection (b)(3)(A) is overly broad and would require a review of chemicals not on the Chemical of Concern lists.

§ 69505.4(a)(2).B and C Alternatives Analysis: Second Stage

Multimedia life cycle impacts and chemical hazards for chemical ingredients known to be in the Priority Product and the alternatives are to be disclosed. This means manufacturers need to disclose the full composition of their product, but per 69501.1(a)(33), they cannot claim Confidential Business Information protection unless the chemicals are totally hazard free. This means manufacturers’ proprietary compositions will be publicly disclosed, resulting in a large transfer of intellectual property to foreign competitors. The hazard constraints on what can be claimed as a trade secret need to be narrowed.

CSPA is concerned that the provisions of § 69505.5 are excessively broad. The amount of information that the Department proposes should be collected will render implementation of the regulation burdensome for the Department and industry. Moreover, a regulatory framework with more reasonable parameters would satisfy the intent of the Statute. The requirement that responsible entities provide the name and contact information for all parties who purchased products within the last 12 months is wholly unnecessary, and a task that will require hours of manpower in and of itself. CSPA requests the deletion of the provision.

§ 69505.5 Alternatives Analysis Reports

CSPA is critically concerned that trade secrets and confidential business information is properly protected during the public review and report process of the Alternatives Analyses.

§ 69505.5(d)(4)

CSPA objects to the request for a list of all retail sales outlets. In many cases manufacturers work through distributors and therefore may not have readily available the identification and location of retail sales outlets. It is also unclear if the Department has the statutory authority to request retail sales information if it occurs outside of the state of California or via the internet. In addition, retail sales information is often proprietary information and goes beyond the statutory authority of the Department.

§ 69505.5(d)(5)

CSPA is concerned about the lack of clarity in disclosure of the location(s) of manufacturing plants and/or the proximity to sourced materials. CSPA is very concerned that this would

disclose proprietary information or severely impinge on supplier-manufacturer relationships. This requirement should be eliminated or narrowed significantly.

§ 69505.5(e)(3)

CSPA is concerned about the disclosure of basis Chemical of Concern plus all other Chemicals of Concern and recommends that this section includes a provision of an Alternatives Analysis Threshold Exemption level consistent with § 69503.5.

§ 69505.5(i)(2)(C)

CSPA is concerned about the request for full ingredient disclosure in final Alternatives Analysis. As noted “A list of all chemical ingredients known, based on available information, to be in the selected alternative that differ from the chemical ingredients in the Priority Product or that are present in the selected alternative at a higher concentration than in the Priority Product” is highly problematic and the benefit or relevance of disclosing this information is not clear.

CSPA recommends voluntary ingredient dictionaries such as the CSPA Consumer Product Ingredient Dictionary²⁰ for disclosure nomenclature to ensure clear identification while maintaining adequate protection of Confidential Business Information.

§ 69505.5(j)(2)(C)

CSPA is concerned that this section significantly impacts innovation and inhibits reformulation due to the limitations on Confidential Business Information claims. Due to the breadth and scope of the various hazard traits and the corresponding lack of any risk considerations, virtually no chemicals would be considered “hazard free”, consequently Confidential Business Information claims would be precluded or very limited. The selected alternative would most likely be Confidential Business Information but per § 69501.1(a)(33), responsible entities cannot claim Confidential Business Information unless *totally* hazard free.

CSPA recommends that the Department clarify these issues to ensure Confidential Business Information and Trade Secret protection and subject the revision to further public comment.

§ 69505.5(k)(2)(B)

CSPA is concerned about the lack of clarity in that a responsible entity “may” propose a regulatory response, but this seems to presuppose that a regulatory response requirement will be forthcoming from the Department.

CSPA recommends that the Department clarify the identification of regulatory responses that may be suggested by the implementation plan. It may also be helpful to add “significant” to “adverse public health and environmental impacts” to indicate an appropriate threshold consistent with CEQA. CSPA also requests an Alternatives Analysis Threshold level under which no regulatory response is required.

²⁰http://www.cspa.org/index.php?page=shop.product_details&flypage=flypage.tpl&product_id=21&category_id=6&vmcchk=1&option=com_virtuemart&Itemid=32

§ 69505.6(c)(1) and (2) Department Review and Determinations for AA Reports

CSPA is concerned about the lack of clarity that this section implies that product information and End-of-Life considerations (if hazardous waste) will be automatically required for all alternatives or Priority Products.

CSPA recommends that the Department take into account the economic impacts upon small business and ensure that the regulatory response adheres to the most cost-effective options.

§ 69506 Regulatory Response Selection Principles

CSPA has concerns about an “alternative of least concern” being patented and being dictated to marketplace.

§ 69506.2 (a) and (b) AA Report Supplemental Information Requirements

CSPA objects to the lack of a specified timeframe by which the Department may request supplemental information and to the lack of discernible limits to information call-in authority. This section provides that the Department “may at any time” require the responsible entity to “provide any information” and/or “obtain or develop information to fill one or more of the information gaps...” The Department has indicated that its intent is not to require the generation of information in order to fill data gaps. This provision appears overly broad and contrary to that stated intent.

CSPA recommends that the Department revise this section for consistency with prior statements of intent.

§ 69506.4(a)(1) Product Information for Consumers

CSPA is concerned that the very large number of Chemicals of Concern plus the cumulative definition of the Alternatives Analysis threshold (the total concentration of all chemicals of concern exhibiting the same hazard trait, environmental or toxicological endpoint, and mode of action) means that most products will require extensive labeling. It is unclear if the Department has considered how that requirement will interfere with existing labeling regulations that already strain limited label space, especially for smaller-sized products. The Department’s suggested alternatives (an accessible manual or point-of-sale posting) are inflexible given the sheer variety of products that may be subject to Alternatives Analyses as the program proceeds.

If an alternative is not selected, the Department should require identification of only the Chemical(s) of Concern that caused the priority product listing in the first place. If an alternative is selected that contains Chemical(s) of Concern, only those Chemical(s) of Concern that serve the same function as the replaced Chemical of Concern should be required to be identified. Otherwise, the manufacturer will be placed at an unfair disadvantage relative to competitive products that did not happen to contain the Chemical(s) of Concern that caused the priority product listing, but may contain other Chemical(s) of Concern.

CSPA also requests that any requirement for labeling be 24 months to allow sufficient time for appropriate distribution throughout commerce and allow a sell through provision for existing inventory.

CSPA also requests a provision to allow an exemption if the Alternatives Analysis shows no adverse effects to human health and the environment.

§ 69506.4(a)(1)(A)

CSPA recommends that the Department follow Federal Trade Commission requirements for whom to name. In many cases, especially for importers, the name of the manufacturer is Confidential Business Information.

§ 69506.4(a)(1)(B)

CSPA is concerned about the lack of clarity with what is meant by “description of the product.” Is the description of the product per the label as sold per current labeling laws sufficient such as the generic soap, shampoo? Is there relief for manufacturer, retailer if the consumer uses it inappropriately and causes issues based on some unknown interpretation? CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

CSPA recommends that the Department clarify this concern and subject the revision to further public comment.

§ 69506.4(a)(1)(C)

CSPA questions the requirement to list of all known Chemical of Concerns regardless of whether there is an Alternatives Analysis threshold level. This section appears to be in conflict with § 69506.4(a)(2) which indicates that this section does not apply. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

§ 69506.4(a)(1)(F)

CSPA is concerned about the lack of clarity of what information would suffice for industrial purposes. Namely, would a Safety Data Sheet (SDS) available on the internet suffice for industrial products? We believe that this should be explicitly considered adequate by the Department. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

§ 69506.4(a)(2)

CSPA is concerned there is a lack of clarity between this section and the previous section if a Priority Product contains a Chemical of Concern below the Alternatives Analysis threshold. This section appears to be in conflict with § 69506.4(a)(1)(C) which indicates that this section does apply. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

§ 69506.4(b)

CSPA is concerned that requiring point of sale posting is inherently difficult. Most retailers are not equipped to handle additional posting of information that is not covered by product labeling. For example, customers typically have to go to the store bulletin board to view consumer product recalls. Also, manufacturers should not be liable if a retailer fails to execute a point of sale

posting. This measure is impractical given the number retail outlets potentially impacted, for example, thousands of gas stations across the state.

Labeling is the standard approach and CSPA recommends removal of the provision to post information at point of sale display in § 69506.4(b)(2)(B)).

§ 69506.6 Product Sales Prohibition

CSPA objects to the assumption the Department will be able to judge whether a safer alternative exists that is both functionally acceptable and technologically and economically feasible. It is simply not within a state agency's capability to determine whether a safer alternative meets those criteria. Such a draconian action should not be undertaken unless significant adverse impacts are identified that make it necessary to protect public health and the environment, and the Department undertakes a rulemaking seeking to prohibit sales which allows for public review and comment.

§ 69506.6(a)

CSPA is concerned about the lack of clarity with the exemption for no Chemical of Concern above Alternative Analysis threshold provision. Does this apply to only the basis Chemical of Concern or all Chemical of Concerns? Only the basis Chemical of Concern would have an Alternative Analysis threshold. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

§ 69506.6(b)

CSPA recommends there be a scientific peer review, as well as, a notice and comment period when the Department determines there is a safer alternative.

§ 69506.6(d)(1)

CSPA recommends there be a scientific peer review, as well as, a notice and comment period when the Department determines there is no safer alternative and there is no public health/environmental benefit to the product.

§ 69506.8 End-of-Life Management Requirements

CSPA requests an amendment to clarify the end-of-life management requirement is only invoked as necessary to protect public health and the environment, i.e., "DTSC may require an end-of-life management program if needed to assure public safety and the environment."

In addition, how does this affect products that are hazardous waste as sold, but are no longer considered hazardous after complete use by the consumer? How does this section impact local and state waste disposal sites without being burdensome and cost prohibitive?

CSPA recommends that the Department provide an exemption for end-of-life management of low volume products. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

In addition, in subdivision (c), the Department apparently seeks to exempt existing extended producer responsibility programs. However, it does not state it specifically. Rather, it authorizes the responsible entity to substitute an alternative end of life management program that achieves

“to the maximum extent feasible, the same results as the program required by this section.” It provides that a responsible entity may not substitute an alternative end of life management program unless it receives advanced written approval from the Department. Hence, a responsible entity could subject to both an end of life management program administered by the Department as well as by its sister agency, Cal Recycle. This would be in conflict with the underlying statutory authority that prohibits the Department from duplicating or adopting conflicting regulations for product categories already regulated or subject to pending regulation.²¹

§ 69506.9 Advancement of Green Chemistry and Green Engineering

CSPA is concerned about the requirement of a manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product that uses green chemistry and/or green engineering principles. CSPA questions how this project would be monitored and enforced and if there would be penalties for non-compliance. CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed Regulation.

§ 69506.10 Regulatory Response Selection and Re-Evaluation

CSPA is concerned that this provision could mean that a responsible entity invests significant capital in undertaking a regulatory response imposed by the Department, only to be told that the Department has changed its mind, and would instead like to impose a different regulatory response. The threat of this sort of outcome is certain to have a chilling effect on business and innovation in California. Additionally, there should be a point where the responsible agency is deemed to have complied with its obligations under the rules and the process is concluded, as opposed to a never-ending re-evaluation of the chemical and product combination. If new evidence of a concern appears, the product and chemical combination should once again go through a meaningful product prioritization process.

CSPA is also concerned that patented alternatives could be permitted or mandated under the existing language which may be costly and restrictive to consumers to promote one chemical or regulatory response over another.

CSPA suggest that subsection (b) be deleted in its entirety and add a regulatory response of “No further action required.” CSPA also suggests that the Department add a provision for public review and comments in a formal rulemaking process on any proposed regulatory responses.

§ 69506.11 Exemption from Regulatory Response Requirements

CSPA is concerned that this section does not adequately address regulatory duplication. For example, subdivision (b) of the statutory section provides that, “This article does not authorize the Department to supersede the regulatory authority of any other department or agency.” Subdivision (c) provides that, “The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.” § 69506.11 of the regulation place the burden on the

²¹ Health and Safety Code § 25257.1(c).

responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response “substantially duplicates” one or more requirements of another California or federal regulatory program, “without conferring additional public health or environmental protection benefits.” There are several concerns with this section: The Statute does not impose the burden on the responsible entity to apply for an exemption. In fact, the Statute explicitly prohibits the Department from regulatory duplication, providing the article does not authorize the Department to supersede, duplicate, or adopt conflicting regulations.

Second, with respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. Again, this exceeds the Department’s authority. Nothing in this section with respect to duplication contemplates that the Department or the Department may duplicate other regulatory programs if the Department is conferring greater public health or environmental protection.

It appears the Department has ignored the fact that subdivision (b) of Health and Safety § 25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. The imposition of a program, even if it provides additional public health or environmental protection, supersedes the other agency’s regulatory program. The Department is specifically prohibited by Health and Safety § 25257.1 from doing that.

CSPA requests clarification and opportunity for additional public comment on any subsequent change to the proposed regulation.

§ 69506.12 Regulatory Response Report and Notifications

Responsible entities should be required to send notice only to those to whom they “directly” sell. The responsible entity cannot and should not be required to notify third party sellers, e.g., eBay.

Products produced by manufacturers may be sold in non-traditional retail outlets outside such as swap meets, deep discount stores and online marketplaces (e.g., eBay). In most cases, the manufacturer and/or distributor has no relationship with the operators of these outlets and has no control over the sale of brand name or other products they produce. Therefore, CSPA requests that the language take such circumstances into consideration by allowing manufacturers to take “reasonable prudent precautions” to avoid non-complying products shipped for sale and use outside of California from being sold in the state as well as for products which may appear at retail outlets over which the manufacturer has no control.

The timing for such notification also needs to be lengthened; as such notifications will be a burdensome task.

§ 69507.4 Time Lines for Requests for Review

CSPA is concerned that there is no provision for revisiting a decision after the review period. For example, what if a problem arises during implementation that shows the department's decision was ill-advised?

CSPA recommends that the Department add periodic review of five years for a completed Alternatives Analysis.

§ 69508 Qualifications and Certification for Assessors

CSPA thinks the Accreditation Bodies and Certified Assessors plan, as described in the proposed regulation, is unworkable. As noted above, academic knowledge in various fields, without significant experience in formulation, processing, or manufacturing consumer products does not provide enough knowledge to become accredited to train and certify assessors. In many cases those conducting an Alternatives Analysis will have significantly more experience than the accreditation body, a case which could lead to significant issues when there are disagreements.

The proposed accreditation program is unnecessarily bureaucratic and will not provide better assessors, since company expertise will still be the tools that companies will use to determine better alternatives, as they have done for many years. The accreditation program proposed (see § 69505.1.(e) Certified Assessors) would be better suited to helping develop guidelines for conducting an Alternatives Analysis and to provide additional training to the Department in areas where staff members are not already experts.

§ 69510 Trade Secret Protection

CSPA is extremely concerned that the proposed regulation is not legally defensible, exceeds statutory authority and is inconsistent with California Civil Code. The case for ensuring adequate protection of intellectual property right and trade secret and other confidential business information (CBI) is straightforward, practical, and steeped in the history of American business ingenuity and success. American companies have relied on this protection of their most valuable intangible asset from disclosure to competitors to support innovation and growth. For these reasons, trade secrets and other CBI must be carefully safeguarded from competitors to ensure a financial return on the significant costs of research and development (R&D) and to preserve brand integrity and distinction.

As a means to being appropriately protective this Article should address “Confidential Business Information,” which includes not only trade secrets, but also commercial or financial information that is privileged or confidential. Moreover, it must set forth a protocol that contains information security systems, employee protocols and training to assure that the Department has the ability to protect trade secret information that is supplied in connection with the July 2012 Proposal. To our knowledge, the Department does not have such a protocol in place, and without it, there is no means to actually ensuring that trade secret information is actually protected, even if it is the Department’s intent to do so.

§ 69510(a)(6) Assertion of a Claim of Trade Secret Protection

CSPA questions the legal defensibility and the need for the estimated value of the information to the person and the person's competitors as this information has no statutory basis.

CSPA recommends removal of this provision.

§ 69510(a)(7)

CSPA questions the legal defensibility and benefit and relevance of providing the estimated amount of effort and/or money expended by the person in developing the information. The amount of effort or money to develop trade secrets has nothing to do with whether it is a trade secret (serendipitous discoveries do occur).

CSPA recommends removal of this provision.

§ 69510(a)(8)

CSPA questions the legal defensibility and the need to submit information on the ease with which chemical identity is or is not readily discoverable.

CSPA recommends removal of this provision.

§ 69510(a)(10)

CSPA questions the legal defensibility and the need to describe the nature and extent of harm of disclosure.

CSPA recommends removal of this provision.

§ 69510(e)

CSPA is concerned about documentation supporting a claim of trade secret protection which contains information that is itself subject to a claim of trade secret protection. This section of the regulation should focus on the interrelationship of the new Safer Consumer Products law with the preexisting California laws on trade secrets. California Civil Code § 3426.1 provides,

(d) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

(1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and

(2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one should show that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by the Department under California Health and Safety Code § 25257(d) should logically begin by looking at those two questions.

Thus it would be reasonable to approach the question of supporting a claim of trade secrecy by asking the submitter to provide information relevant to items (1) and (2) above and relevant to the difficulty of discovering the information through analyzing the product. Much of the current draft regulation § 69510 is not needed in order to show that submitted information meets the definition of a trade secret under California law, and those items should not be required of the person (company) claiming trade secret rights.

Further, given that, under § 69510(f) of the draft regulation, trade secret protection may not be claimed for information identifying or describing a hazard trait exhibited by a chemical or chemical ingredient, there is no reason why the lengthy and intrusive list of questions in the draft regulation is necessary. Answering all of those questions for each trade secret claimed will be a burden requiring needless expenditure of resources by trade secret owners, adding cost to consumer products.

It is worth pointing out that the Statute which these draft regulation purport to implement says in Health and Safety § 25253(c):

(c) The department, in developing the processes and regulations pursuant to this section, shall ensure that the tools available are in a form that allows for ease of use and transparency of application. The department shall also make every feasible effort to devise simplified and accessible tools that consumer product manufacturers, consumer product distributors, product retailers, and consumers can use to make consumer product manufacturing, sales, and purchase decisions.

The current draft regulation fails to fulfill the aspiration set forth in this Statute. In their treatment of trade secrets, they do not ensure a process that is easy to use, nor are they simplified tools that manufacturers, distributors, and retailers can use.

CSPA requests protection of confidential business information which may not be considered "trade secret."

§ 69510(f)(g)

CSPA is critically concerned given the broad definition of hazard trait under Chapter 54 of this regulation, very little will be able to be claimed as trade secret.

CSPA recommends that the Department carefully review existing Trade Secret protections, modify the regulation to achieve compliance accordingly and obtain further public comment.

§ 69510(g)

CSPA is very concerned that trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the claim is for a proposed alternative to a Chemical of Concern in a Priority Product subject to certain requirements. Those requirements include demonstrating to the Department's satisfaction the chemical is a new chemical or a new use of an existing chemical, providing the Department with sufficient health,

safety, and environmental data to demonstrate that it is substantially safer than the existing Chemical of Concern of the Priority Product, and complying with the substantiation requirements of subdivision(a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret. Finally, the proposed regulation provides no clarification to the regulated community of what constitutes a “new use,” for which DTSC and responsible entities may have vastly different interpretations.

CSPA recommends that the Department carefully review existing Trade Secret protections, modify the regulation to achieve compliance accordingly and obtain further public comment.

In addition, CSPA is concerned with how “substantially safer” is measured to ensure consistency in the marketplace and the definition should be revised to include criteria that can be easily understood and referenced.

§ 69510.1 Department Review of Claims of Trade Secret Protection

In order to ensure that the Department Review process for claims of trade secret protection is consistent and affords the submitting company protection for the trade secret information throughout the review process, CSPA recommends the following changes:

- (a) Upon receipt of information submitted under this chapter that contains information identified as being subject to trade secret protection, or at any time thereafter, the Department may review the trade secret claim ~~and supporting information~~ for compliance with the requirements of this article.
- (b)(1) If the Department determines that information provided in support of a request for trade secret protection is incomplete ~~or insufficiently responsive to permit a trade secret determination~~, the Department shall:
 - (A) Notify the submitter of the Department's finding of ~~insufficiency incompleteness~~;
 - (B) Identify the specific area(s) for which additional information is needed;
 - (C) Provide an explanation as to why the Department has determined the information to be insufficient; and
 - (D) Indicate the date by which the submitter must provide the requested information.
- (2) If the submitter fails to provide the information within the timeframe specified, the Department shall notify the submitter by certified mail that the claim is out of compliance with this article, and inform the submitter that the information claimed to be trade secret ~~will be considered a public record subject to disclosure by~~ must be provided to the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief.
- (c) ~~If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall notify the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department thirty (30) days after such notice is mailed. During this 30-day period, the submitter may seek judicial review by filing an action for a preliminary~~

~~injunction and/or declaratory relief.~~ (d) If a person asserting a claim of trade secret protection initiates an action under subsection (b) ~~or (c)~~, the Department may not publicly release or disclose the information that is the subject of the claim of trade secret protection until resolution of any court challenge, including appeals, if any.

Concerns with Initial Statement of Reasons

CSPA is concerned with the lack of clarity with the definition of “Adverse impacts”.

CSPA recommends that the definition be revised to include quantitative thresholds that can be easily understood and referenced during the research and development and Alternatives Analysis process, and so that the process for selecting Priority Products is appropriately transparent.

In addition, § 69501.1(a)(5) defines an “adverse environmental impacts” and refers one to “subsection (E)” for clarification of when a chemical exceeds an enforceable standard and the occurrence of an adverse impact. Subsection (E) does not exist in either regulation.

CSPA recommends that the Department revise the text accordingly to address the lack of clarity.

Summary and Conclusions

CSPA appreciates the opportunity to comment on the Safer Consumer Product Regulation and remains supportive of the principles of Green Chemistry and programs that are consistent with those principles.

Our member companies engage in Alternatives Analyses everyday as they seek to innovate and develop products that are efficacious and desirable in the marketplace. As always, CSPA remains steadfast in our commitment to manufacturing and marketing safe products that are protective of human health and the environment while providing essential benefits to consumers. The Safer Consumer Products Regulation can provide an effective means to assess and make determinations about certain chemicals in commerce but it must also be functional for the regulated community. In fact, our initial support for the Green Chemistry Initiative and the Statute underlying this regulation was predicated on just that belief.

We appreciate the significant stakeholder outreach and communication; however, we continue to believe further work must be done to make this regulatory process science-based, economically and technically feasible, and workable for both DTSC and the regulated community.

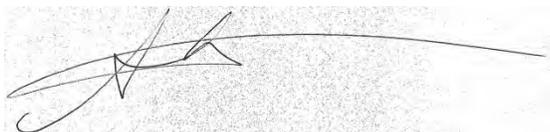
As detailed in the preceding comments, CSPA has identified major areas of concern, including failure to comply with Administrative Procedures Act process, lack of justification for the CEQA Notice of Exemption, failure to adequately address requirements to prevent regulatory duplication, inadequate protection of Confidential Business Information and Trade Secrets, lack of clarity and scientific foundation of the Priority Product process, and the lack of an internationally harmonized Alternative Analysis Threshold Exemption level. We appreciate the significant stakeholder outreach and communication; however, we continue to believe further work must be done to make this regulatory process science-based, economically and technically feasible, and workable for both the Department and the regulated community.

Please contact us if you have questions regarding our comments.

Respectfully submitted,



D. Douglas Fratz
Vice President, Scientific & Technical Affairs



Steven Bennett, Ph.D.
Director, Scientific Affairs



Kristin Power
Director, State Affairs – West Region

cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency
Miriam Ingenito, Deputy Secretary, California Environmental Protection Agency
Kristin Stauffacher, Assistant Secretary, California Environmental Protection Agency
Michael E. Rossi, Senior Advisor for Jobs and Business Development,
Office of the Governor
CSPA Scientific Affairs Committee Green Chemistry Task Force
CSPA State Government Affairs Advisory Committee
Laurie Nelson, Randlett/Nelson/Madden

October 9, 2012

Director Debbie Raphael
California Department Toxic Substances Control
Public Comments: Department Reference Number: R-2011-02
Office of Administrative Law Notice File Number: Z-2012-0717-04

Dear Director Raphael,

As an active participant on the roll out of the Regulations regarding AB 1879 I'd like to forward these comments for your consideration.

The law was inspired to foster continuous innovation by the industry in the design and manufacture of consumer products in order to reduce the impacts of those products on Californians and their environment.

The program that we run at the Cradle to Cradle Products Innovation Institute was located in California to help facilitate the move to safe and healthy materials and processes as the result of the passage of AB 1879. In the intervening four years, we have worked to take what was a private proprietary methodology and to bring it into the public domain as a public and transparent tool.

The Cradle to Cradle Certified^{CM} Products Program is a multi-attribute program that assesses products for safety to human and environmental health, design for future use cycles, and sustainable manufacturing processes.

Unlike single-attribute eco-labels, the certification program takes a comprehensive approach to evaluating the design of a product and the practices employed in manufacturing the product. Each product is evaluated in five categories: Material Health, Material Reutilization, Renewable Energy Use, Water Stewardship, and Social Responsibility. Products can be Cradle to Cradle Certified^{CM} at one of four levels (Basic, Silver, Gold, or Platinum) based on achievement against criteria in all five categories.

Cradle to Cradle Certified^{CM} has been adopted by businesses ranging from large global corporations to small, innovative start-ups, cumulatively representing some trillion dollars in revenue. Hundreds of products have been "certified", receiving a prestigious mark of approval that confirms that

both the product and the company have moved beyond “less bad” to “more good” business practice.

In May of 2010, Braungart and McDonough, authors of Cradle to Cradle, licensed 20 year’s worth of their certification methodology to our non-profit organization. They felt that by bringing Cradle to Cradle Certified^{CM} to the public domain, its ideas and methodologies could spread much farther, much faster to provide the solutions for which the world was desperately searching.

We are now beginning to roll out the public standard and training others who can learn the “how” and “why” of our certification program.

The “Certification Optimization Plan” required for certification is close to the requirements outlined as part of the AB 1879 Alternative Analysis – and goes one step further. The Certification Optimization Plan incentivizes continuous improvement because as soon as a company knows what’s in their product (down to the parts per million) across multiple supply chains they work to start replacing all unsafe materials or unknown materials with healthy, safe substitutes.

We are working to provide optimization training to be inline with your own Alternatives Analysis. We will work to be auditable and transparent in our efforts to show that our program will comply with the outlined requirements.

Currently, Cradle to Cradle certification assessment covers the human and environmental health criteria of most existing models; in addition, it uniquely provides coverage of the life-cycle assessment portion, and adds a section on social responsibility.

We believe that our certification process provides a platform for getting to the new materials and products of the future.

We understand the frustrations of limited budgets in these tough fiscal times and are concerned that under the current regulatory design proposed, the Department may only get to five (5) products in the next five (5) years. We urge DTSC to consider providing an accelerated pathway for those product manufacturers who voluntary seek certification. This can be accomplished in a number of different ways. In this letter, we merely identify a few for your consideration. For instance, DTSC could deem the Cradle to Cradle certification process the functional equivalent of its alternatives analysis. Or,

DTSC could provide an alternative expedited regulatory pathway for products that have received Cradle to Cradle certification. Or DTSC could determine that Cradle to Cradle certified products are not subject to the regulations, or that Cradle to Cradle certified products will receive a 3 year reprieve in being selected as a priority product if they are on schedule with their optimization plans.

We are open to a discussion of any of the above listed options and more. We think it is critically important that green chemistry and the move to safer products are accelerated. Five (5) products in five years is not going to be sufficient. The draft regulations need to reward and incentivize voluntary behavior to move entire industries in the direction of safer materials. We urge you to support the inclusion of the Cradle to Cradle Certified^{CM} assessment as an important tool to accelerate the goals of the green chemistry statute and the mission of the Department.

Sincerely,

A handwritten signature in black ink that reads "Bridgett Luther". The signature is written in a cursive style and is positioned above the typed name.

Bridgett Luther, President

October 9, 2012

Director Debbie Raphael
California Department Toxic Substances Control
Public Comments: Department Reference Number: R-2011-02
Office of Administrative Law Notice File Number: Z-2012-0717-04

Dear Director Raphael,

As an active participant on the roll out of the Regulations regarding AB 1879 I'd like to forward these comments for your consideration.

The law was inspired to foster continuous innovation by the industry in the design and manufacture of consumer products in order to reduce the impacts of those products on Californians and their environment.

The program that we run at the Cradle to Cradle Products Innovation Institute was located in California to help facilitate the move to safe and healthy materials and processes as the result of the passage of AB 1879.

Cradle to Cradle Certified^{CM} is a multi-attribute program that assesses products for safety to human & environmental health, design for future use cycles, and sustainable manufacturing processes.

Unlike single-attribute eco-labels, the certification program takes a comprehensive approach to evaluating the design of a product and the practices employed in manufacturing the product. Each product is evaluated in five categories: Material Health, Material Reutilization, Renewable Energy Use, Water Stewardship, and Social Responsibility. Products can be Cradle to Cradle Certified^{CM} at one of four levels (Basic, Silver, Gold, or Platinum) based on achievement against criteria in all five categories.

Cradle to Cradle Certified^{CM} has been adopted by businesses ranging from large global corporations to small, innovative start-ups, cumulatively representing some trillion dollars in revenue. Hundreds of products have been "certified", receiving a prestigious mark of approval that confirms that both the product and the company have moved beyond "less bad" to "more good" business practice.

In May of 2010, Braungart and McDonough, authors of Cradle to Cradle, licensed 20 year's worth their certification methodology to our non-profit organization. They felt that by bringing Cradle to Cradle certified to the public domain, its ideas and methodologies could spread much farther, much faster to provide the solutions for which the world was desperately searching.

We are now beginning to roll out the public standard and training others who can learn the “how” and “why” of our certification program.

We believe that our certification process builds on the Alternatives Analysis and provides a platform for getting to the new materials and products of the future.

The “Certification Optimization Plan” required for certification is close to the requirements outlined as part of the AB 1879 Alternative Analysis – and goes one step further. The Certification Optimization Plan incentivizes continuous improvement because as soon as a company knows what’s in their product (down to the parts per million) across multiple supply chains they work to start replacing all unsafe materials or unknown materials with healthy, safe substitutes.

We are working to provide optimization training to be inline with your own Alternatives Analysis. We will work to be auditable and transparent in our efforts to show that our program will comply with the outlined requirements.

Currently, Cradle to Cradle certification assessment covers the human and environmental health criteria of most existing models; in addition, it uniquely provides coverage of the life-cycle assessment portion, and adds a section on social responsibility.

We urge you to support the inclusion of the Cradle to Cradle certified^{CM} assessment as a unique option among existing models for Alternatives Assessment.

Sincerely,



Bridgett Luther, President



October 4, 2012

Via email gcregs@dtsc.ca.gov

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

On behalf of Creative Nail Design, Inc., I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("Regulation") of July 2012.

Founded in 1979 and based in Vista, CA, Creative Nail Design, Inc. ("CND") is the global leader in professional nail, hand and foot beauty. Deeply committed to advancing the nail care industry, CND devotes significant time and resources to product research and development, education, and customer support. CND is an industry-leading advocate for the role of nail care in personal beauty and fashion.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that DTSC has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable DTSC to pilot this unique program and to learn what works and does not work and make adjustments accordingly.

Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and **far in excess of that which its own resources can support**. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose **true risks** for human health and the environment, based on hazard, exposure and the likelihood of harm (i.e. those items for which serious injuries or deaths have already occurred). We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

Creative Nail Design, Inc.
1125 Joshua Way
Vista, CA 92081 USA

760.599.2900
www.cnd.com

BACKGROUND POINTS

- Article 1, 69501(b) - The Regulation fails to provide upfront exemption under the overall applicability for regulatory duplication. It is deficient in that it is less broad than that required by the authorizing statute that provides that DTSC shall not supersede the authority of another regulatory agency.
- Article 1, Definitions - The Regulation lacks harmonization with Federal and International definitions.
- The Regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. DTSC has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).
- One of the most concerning aspects of the proposed regulation as currently drafted is the latitude which DTSC reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach based on reducing REAL, already demonstrated, not theoretical, RISK.
- Full implementation of the regulation as drafted would necessitate a huge new government program with a **substantial budget requirement**.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on REAL exposure and

hazard, not theoretical, and it must avoid duplication and conflicting regulatory requirements.

- o The Regulation proposes to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. *This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.* No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- o GCA supports this two step approach, i.e., “chemicals under consideration” and “chemicals of concern.” In this regard, we concur with GCA’s recommendation that DTSC begin by identifying their list of 1200+ chemicals of “Chemicals Under Consideration.” DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. *A discrete subgroup of these chemicals with exposures in California that have already resulted in proven harm should be identified as Chemicals of Concern.*
- In addition to the 14 lists and eight governmental programs, the Regulation provides that DTSC may add chemicals which meet only one of 16 factors. Everything, including air and water, meet at least one of those factors. A more refined and specific requirement needs to be outlined for adding chemicals.
- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

Ms. Krysia Von Burg
Comments on Safer Consumer Product Alternatives Regulation (July 2012)
October 4, 2012
Page 4 of 4

- The Regulation threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.
- The Regulation threatens the basic tenant of US entrepreneurial principles by potentially forcing all manufacturers of a given product to utilize a favored technology, thereby eliminating the California consumer's right to choose.
- DTSC has overlooked one very basic principle: Manufacturers of consumer products constantly strive to make better products, that is, products that perform effectively, that are reasonably priced, beneficial and safe for use and disposal. These efforts are motivated by a commitment to sustainability, the need to compete in the marketplace and to avoid causing harm. The Regulation as proposed will place an undue burden and will not provide a real benefit to Californians.

We appreciate your consideration of our concerns. For further information or questions, please contact Debbie Waite at 760-599-2900. Thank you!

Sincerely,



Debbie Waite
Manager, Regulatory Affairs

cc: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

DAIMLER

Daimler Trucks North America
Sean Waters
Director
Compliance and Regulatory Affairs

October 11, 2012

Ms. Debbie Raphael
Director
California Department of Toxic Substances Control
1001 "I" Street
Sacramento, California 95812

Re: Comments on the DTSC's Proposed Safer Consumer Product Regulations

Ms. Raphael,

On July 27, 2012, the California Department of Toxic Substances Control (DTSC) released its Safer Consumer Products Proposed Regulations. The proposed regulations describe a four-step process to identify safer consumer product alternatives applying to products sold and used in California including "highly durable products" such as those manufactured by Daimler Trucks North America LLC (DTNA) and its engine manufacturing division, Detroit Diesel Corporation (DDC). DTNA appreciates the opportunity to submit comments on the proposed regulations.

DTNA recognizes the importance of protecting consumers from chemicals of concern (COCs) and complies with all applicable federal and state regulations in both the manufacture and design of our products. In fact, DDC was one of the first heavy-duty engine manufacturers to be certified to ARB's stringent 0.2 gram/brake horsepower-hour (g/bhp-hr) standard and to apply for early certification to the new 2014 U.S. Environmental Protection Agency (EPA) / National Highway Traffic Safety Administration (NHTSA) engine greenhouse gas (GHG) and fuel efficiency regulations (GHG14). DTNA's vehicle manufacturing divisions: Freightliner, Western Star, Freightliner Custom Chassis, and Thomas Built Buses, were the first to be certified to the new GHG14 standards - certifying DTNA's entire product line a year early and before any other manufacturer certified any portion of theirs.

Multiple state and federal agencies already regulate heavy-duty trucks and engines.

On-highway tractors and the diesel engines that power them are subject to extensive environmental and safety regulations by numerous entities including the California Air Resource Board (ARB), EPA, NHTSA, Federal Motor Carrier Safety Administration (FMCSA), Occupational Safety and Health Administration (OSHA), Consumer Product Safety Commission (CPSC), and other state regulatory bodies. Exhaust gases are regulated. Fuel efficiency is regulated. Noise is regulated. Engine rebuilding practices are regulated. Destruction of the vehicle at the end of its life and recovery of hazardous materials are regulated. Effectively, nearly every aspect of a truck's life is already strictly controlled from manufacture to destruction and their usage in-between.

Heavy-duty truck diesel exhaust and GHG emissions are already tightly controlled.

Today's diesel engines are often referred to as "Clean Diesel" by regulatory entities such as the ARB, and must meet extremely stringent criteria pollutant standards (e.g. NO_x, particulate matter, hydrocarbons, carbon monoxide, and more all being subject to standards) as well as meet strict GHG standards. In addition to engine emission standards and engine and vehicle GHG standards, the California Diesel Fuel Program regulates the fuel that powers these vehicles, and California Vehicle Code Section 27156 and the Federal Clean Air Act prohibit modifications (such as the installation of certain aftermarket or performance parts) that increase motor vehicle emissions. EPA compliance testing programs that include Selective Enforcement Audits, Confirmatory Testing, and In-Use Compliance Testing ensure compliance to emissions standards. In summary, diesel engines and vehicles already comply with a host of stringent regulations, such that adding new regulatory programs is largely duplicative potentially adding regulatory burden without providing additional benefits.

DTNA already complies with California-specific in-use environmental standards.

In-use compliance is strictly enforced through many programs. First and foremost, in-use compliance with emission standards is strictly enforced and comprehensive onboard diagnostic (OBD) regulations ensure that a fault is detected before an engine exceeds an emission threshold. For example, current OBD standards require that in 2013 heavy-duty trucks detect a fault prior to a truck emitting NO_x at a level equal to 0.40 g/bhp-hr. In addition to OBD monitoring which ensures engine emission compliance on a second-by-second basis, California also has other strict in-use requirements, including:

- 1) On-Road Heavy-Duty Diesel Vehicles (In-Use) Regulations require diesel trucks and buses that operate in California to be upgraded to reduce emissions. Heavier trucks must be retrofitted with PM filters beginning in 2012, and older trucks must be replaced starting in 2015. By January 1, 2023, nearly all trucks and buses will need to have engines with aftertreatment reducing NO_x to very low limits (e.g. 2010 model year engines or equivalent.)
- 2) The Heavy-Duty Vehicle Inspection Program requires heavy-duty trucks and buses to be inspected for excessive smoke and tampering, and emission control label compliance.
- 3) The Periodic Smoke Inspection Program requires that diesel and bus fleet owners conduct annual smoke opacity inspections of their vehicles and repair those with excessive smoke emissions to ensure compliance.
- 4) The Manufacturer-Run In-Use Testing Program, overseen by the EPA and ARB, strictly requires testing real-world vehicles and demonstrating that their emissions are within prescribed limits.
- 5) The Heavy-Duty Vehicle Idle Emission Reduction Program requires all engine shutdown after idling for five minutes unless strict idle NO_x emissions requirements are met.
- 6) The Tractor-Trailer Greenhouse Gas Regulations include a field inspection program doing enforcement at California Highway Patrol weigh stations and other random roadside locations, distribution centers, fleet facilities, truck stops and locations where trucks are present.

DTNA already complies with other California environmental truck regulations.

In addition to emission control standards, California regulations also mandate what type of engine coolant can be added to engines used in California (a bittering agent is required in most coolant sold to

prevent poisoning of children and/or animals), how engine and vehicle waste products (such as waste oil) can be disposed of, what type of materials can be used in brake components, refrigerant recovery processes, and even how the wastewater from a truck-wash facility is handled. Processes for removing certain trucks from service are also regulated – including proof of sale outside of the state or proof of destruction (e.g. documentation of frame and engine block mutilation if the vehicle has been destroyed).

DTSC is precluded and preempted from promulgating regulations on products already regulated due to preexisting law.

DTNA believes that in addition to California's Health and Safety Code, Section 25257.1(b), which precludes DTSC from adopting any regulation or requirement of a product already regulated by any other department or agency, and (c) which prohibits regulations duplicative or conflicting with other California regulations, that Section 209(b) and (c) of the Clean Air Act preempt DTSC from this authority. Therefore, DTNA suggests that DTSC should remove its proposed modification (made to the Informal Draft program released by DTSC in October, 2011) that eliminates an upfront exemption for products regulated by other entities and laws "that provide protections with respect to the same public health and environmental adverse impacts and exposure pathways that are addressed by these regulations."

DTNA suggests that DTSC's Safer Consumer Products Proposed Regulation is not designed to be applicable to heavy-duty trucks and engines.

In addition to DTNA's concerns that DTSC is prohibited by statute from regulating products already regulated by any entity, DTNA believes this program is simply not designed to be applicable to engines or heavy-duty trucks which fall under the category of "highly durable products." The summary of proposed regulations document, R-2011-02, describes the program as a set of regulations that "provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives." The program further goes on to describe the intent of the program, which is to require manufacturers of Priority Products to conduct an Alternative Analysis (AA), and describes the process of completing an AA. With the list of COCs including diesel exhaust – DTNA would like to point out that there is no alternative product of combustion other than exhaust. DTNA notes that, even in recent statements regarding the future of air pollution and GHG emission reductions in California, the ARB regards diesel engines as an important part of California commerce in 2050. To require DTNA to complete an expensive and time consuming analysis (including employing a licensed assessor to assist with this analysis) with no other possible outcome of this analysis but to determine that there is no alternative formula or process that can remove or substitute diesel exhaust as a component of our product is simply illogical and unworkable. It is clear from the regulations that the intent of this program is to address the substitution of COCs in products where their inclusion is unnecessary and where nontoxic substitutions are indeed possible. While DTNA applauds the efforts on the part of DTSC to address the dangers to consumers in products where toxic chemicals do not belong, such as lead in children's toys, DTNA does not find this program as fitting to all COCs – and respectfully submits that COCs such as diesel exhaust are indeed already regulated and consumers are already protected by the extensive regulatory efforts already put in place by other agencies such as ARB and EPA. Therefore, DTSC should proceed with the same logic as described in the 2011 Informal Draft that excludes products already regulated by any entity from this program.

DTNA notes that not being considered a stakeholder during the several years this program has been developed further indicates their products were not intended to be included in this program.

Finally, the July 2012 DTSC press release states that “DTSC spent several years working with a diverse group of stakeholders to craft the proposed regulations.” Daimler respectfully notes that their input was not sought even after the change was made to the October 2011 Interim Proposal that would have specifically included them, further indicating that their products were not intended to be included as a part of this program when it was initiated.

Conclusion

DTNA believes that heavy-duty trucks and engines are already regulated by numerous federal and state agencies and that both California statute and the Clean Air Act preclude DTSC from further promulgating regulations – especially duplicative regulations on this industry. Currently, heavy-duty trucks and engines must meet strict criteria pollutant and greenhouse gas emission standards when new, when in-use, and submit to numerous EPA and California inspection programs to ensure they are compliant. DTNA respectfully submits that the intent of this program – to find alternative solutions to COCs in consumer products – is not applicable to heavy-duty trucks and engines, as evidenced by the facts that the alternative analysis does not logically apply to such vehicles and engines and that such truck and engine manufacturers were not considered stakeholders in this program.

Respectfully Submitted

Daimler Trucks North America LLC



October 10, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

On behalf of the Defoamer Industry Trade Association (DITA), I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012. DITA is the leading trade association for suppliers of chemicals with defoaming activity and formulators of defoaming products which are used widely in food processing and in cleaning, lubricant, paint and coating and many other useful products.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

However, we have a number of concerns.

- We remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).
- Most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach.

Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.

- It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on **exposure** and **hazard**, and it must avoid duplication and conflicting regulatory requirements.
 - DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
 - GCA supports this two-step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***
- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community. In addition, in order to assure that priorities are focused on priority products of the most concern, ILMA recommends that 0.1% de minimis level be set for a chemical concern in a product. We believe that this de minimis level should not only be thought as "alternatives analysis" threshold but

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
October 10
Page 3

should be a threshold for any required reporting at all. Potentially, there can be thousands of products with actual or theoretical trace levels of a chemical of concern where the need for reporting would overwhelm DTSC resources and distract the focus on products with higher levels of the chemical of concern.

- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

We appreciate your consideration of our concerns. For further information or questions, please contact me at rich@kraskaconsultants.com or 239-444-1724. Thank you!

Sincerely,



Richard Kraska, Ph.D., DABT
Technical Consultant
Defoamer Industry Trade Association

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



Delta Diablo Sanitation District

OFFICE AND TREATMENT PLANT: 2500 PITTSBURG-ANTIOCH HIGHWAY, ANTIOCH, CA 94509-1373

TEL.: (925) 756-1900 ADMIN. FAX: (925) 756-1961 MAINT. FAX: (925) 756-1963 OPER. FAX: (925) 756-1962 ENGINEERING SVCS. FAX: (925) 756-1960

www.ddsd.org

October 11, 2012

VIA ELECTRONIC MAIL (gcregs@dtsc.ca.gov)

Ms. Debbie Raphael, Director
Department of Toxic Substances Control
Office of Legislation and Regulatory Policy
P. O. Box 806
Sacramento, CA 95812-0806

SUBJECT: COMMENTS ON DRAFT REGULATIONS FOR SAFER CONSUMER
PRODUCT ALTERNATIVES

Dear Director Raphael:

Delta Diablo Sanitation District (District) has long been a supporter of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. The District supports the development of regulations that would promote the re-design of these problem products.

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the Department of Toxic Substances Control (DTSC) website and DTSC should be inviting input from the California Product Stewardship Council and local government agencies and the public prior to approving the plan. The experience of others with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.



Debbie Raphael, Director

October 11, 2012

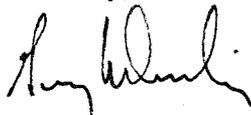
COMMENTS ON DRAFT REGULATIONS FOR SAFER CONSUMER PRODUCT
ALTERNATIVES

Page 2

- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,



Gary W. Darling
General Manager

AWR/GWD:clg

cc: Ms. Heidi Sanborn, California Product Stewardship Council
District File CORP.15.03-CORRES-XX
Chron File



DIRECT SELLING ASSOCIATION

1667 K Street, NW
Suite 1100
Washington, DC 20006
202-452-8666 | 202-452-9010 Fax
www.dsa.org

October 11, 2012

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Green Chemistry Proposed Regulations

Dear Kryisia,

I write concerning the proposed “Green Chemistry Rules,” specifically the addition of chapter 55 to division 4.5 of Title 22, California Code of Regulations. As written, the rules could have a **serious and negative impact on a number of the approximately 2.5 million Californians depending on direct selling** to augment their household income. These Californians sell approximately \$3.8 billion of products in California each year and contribute thousands of dollars in tax revenue to the state.

The Direct Selling Association (DSA) is the national trade association representing over 190 companies that sell products through personal presentation or home parties. Our companies sell and distribute their products through an independent contractor sales force, predominantly made up of individuals working part-time to augment their family income. For purposes of this letter, these individuals will be referred to as distributors. Under the proposed rules, these distributors may fall within the definition of a “retailer” and therefore be subject to overly burdensome disclosure requirements.

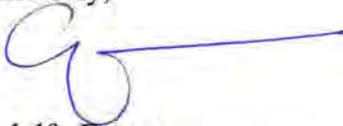
As written, the rules could require distributors to report to consumers specific chemicals contained in the products they contract to sell on behalf of direct selling companies. Imposing such a reporting requirement on these distributors is costly to both the individual distributor and the State. **The adoption of these rules as written could result in reduced sales and have a negative economic impact on California.** Regulatory hurdles will only discourage individuals from taking advantage of direct selling opportunities and hence, reduce revenue in California.

We believe it is unsuitable to place the burden of reporting specific chemicals contained in products on an individual distributor. The proposed regulations cover over 1,200 explicit chemicals with the potential to trigger a duty to disclose. The individual distributor has no control over the chemical composition of the products he/she sells. Nor does the individual

exercise any control as to how products are labeled by a manufacturer. With that in mind, requiring an individual distributor to be responsible for notifying or disclosing chemical contents to his/her customers is an unreasonable expectation.

Accordingly, on behalf of the 2.5 million direct sellers who reside in California, the Direct Selling Association respectfully requests that you **amend the proposed rules** to exempt independent distributors selling products on behalf of direct selling companies from any overly burdensome disclosure requirements.

Sincerely,

A handwritten signature in blue ink, appearing to be 'Adolfo Franco', with a long horizontal line extending to the right.

Adolfo Franco
Executive Vice President
Direct Selling Association



The Dow Chemical Company
Midland, MI 48674
U.S.A.

2040 Dow Center
October 11, 2012

California Department of Toxic Substances Control
Ms. Krysia Von Burg
Regulations Coordinator, Regulation Section
P.O. Box 806
Sacramento, CA 95812-0806

Re: Comments on Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

The Dow Chemical Company (Dow) appreciates the opportunity to provide comments on the final draft regulations for Safer Consumer Products (SCP) released on July 2012 by the California Department of Toxic Substances Control (DTSC or Department).

With over 700 employees and contractors at four manufacturing facilities in California, Dow has a vested interest in these regulations and has been actively engaged in the statutory and regulatory process since its inception. Dow is a diversified company with an industry-leading portfolio of specialty chemicals, advanced materials, agricultural sciences and plastics businesses. Dow delivers a broad range of technology-based products and solutions to customers in approximately 160 countries and in high-growth sectors such as electronics, water, energy, coatings and agriculture. Dow both manufactures and imports chemicals, products and raw materials that are potentially in the scope of this proposed regulation.

As a world leader in using science and technology to shape chemicals management improvements, Dow is well positioned to use green chemistry to address the needs and challenges of a more demanding world. Our commitment to California's Green Chemistry Initiative has been evident with Dow's direct representation on both the DTSC's Science Advisory Panel and the Green Ribbon Science Panel. Dr. Neil Hawkins, vice president of Sustainability & EHS and Dr. Anne Wallin, director of Sustainability & EHS, Europe, Middle East & Africa served for several years on those two deliberative panels, respectively. Dow applauded DTSC's initial goal to incentivize innovation by stimulating principles of green chemistry while minimizing consumers' potential exposure to hazardous chemicals of concern in consumer products.

However, as currently drafted, the SCP Regulations will do little to encourage the innovation of safer consumer products. Instead, it will foster an environment of uncertainty where consumers and participants in the value chain struggle to make

credible, informed choices. The attached addendum outlines specific comments on the proposed regulations. However, Dow's concerns primarily focus on a fundamental premise: the SCP regulations lack clear, objective standards upon which predictability and compliance can be derived.

While Dow recognizes and appreciates the numerous revisions to make the regulations more workable for industry, we urge DTSC to give thoughtful consideration to the areas where the Department could further clarify and simplify the requirements to make them more implementable. As noted in our comments on the initial proposed regulation, we are interested in working with the Department to further optimize the implementation of the regulations for Safer Consumer Products. In addition to our attached comments, we are a member company of the Green Chemistry Alliance (GCA), and we support their comments by reference here.

It is imperative that DTSC be successful with this regulation so that it doesn't collapse under its own weight or add an undue burden on our ailing economy. We look forward to working with DTSC to ensure the effective implementation of this regulation.

Regards,



Connie L. Deford
Director, Product Sustainability & Compliance

Addendum:
Specific Comments on SCP Regulations

Cc:
The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

Specific Comments on SCP Regulations

I. Chemicals of Concern

Dow supports the design of regulations that truly focus on limiting exposure to, and adverse impacts posed by, Priority Products that contain Chemicals of Concern (COCs) in consumer products. This targeted approach encourages the evaluation of chemicals and products of concern where there is a reasonable or foreseeable pathway for exposure. The current Safer Consumer Products (SCP) regulations appropriately recognize that chemicals are to be evaluated based on their individual use in specific products and for identifying a further prioritization process for chemicals found in the initial priority products. However, these regulations do not specify objective criteria by which chemicals might be identified, nor does it state which of the ~1200 chemicals will be listed as COCs.

A. Identification of Chemicals of Concern

The objective of identifying and characterizing COCs is to focus on chemicals used in consumer products that meet specific hazard criteria and have exposure and use patterns that may pose risks. However, by identifying a broad list of COCs compiled by a variety of governmental, intergovernmental and academic interests, it is difficult to truly identify high-priority chemicals. When every chemical is a priority, none will be a priority. The substances on this very large list of COCs will likely remain listed indefinitely, even if they are used safely in consumer products, or even if they are not used in consumer products at all.

There does not appear to be a dedicated public comment period for this initial list of chemicals based on other authoritative bodies. The net effect is that over 1200 chemicals will be on the initial list of COCs without a proper chance for the public to comment on them. The draft thus stigmatizes chemicals and products containing those chemicals from the outset before the regulatory process of alternatives analysis and regulatory response have taken place. This will likely result in unwarranted market impacts because the market will move quicker to product deselection while DTSC struggles to keep pace with the COC identifications. Since the regulations do not include a clear or science-based process by which the DTSC will select which chemicals and products it regulates, the inclusion of such a broad list of COCs does not provide predictability and certainty to companies.

B. Tailored Approach to Chemicals of Concern

Dow supports regulations that are based on established scientific principles that define safe conditions for use and impose requirements to assure that use is controlled within predefined safe conditions. Such a system must rely on risk assessment and risk management principles that are predictable, flexible and

capable of responsibly addressing society's economic, environmental and safety requirements.

Dow suggests that DTSC develop a risk-based chemical management system that screens chemicals to develop a narrower, focused list of COCs that actually represent the greatest potential risk. Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

Dow is concerned that an initial list of some ~1200 COCs will unduly alarm the public without simultaneously providing the public with the confidence needed to ensure timely resolution or disposition of the products that contain those chemicals. DTSC may well be identifying hundreds of chemicals that have little or no use in consumer products, or which pose no risk of harm in those uses.

II. Priority Products

Considering the magnitude of the proposed COC list, Dow believes it is appropriate for DTSC to only designate 2-5 priority products for the first 3-5 years of this program. This approach provides an opportunity for both industry and DTSC to better understand the regulatory challenges of the proposed framework. While Dow supports this approach, this portion of the regulations presents significant concerns for industry.

Dow appreciates that the Priority Products list is apparently intended to be risk-based, as it requires some consideration of exposure and the potential for harm. However, the current regulation identifies a vague process by which DTSC will prioritize and establish a list of Priority Products. It is unclear, however, how DTSC will objectively utilize the "Key Criteria" to assess and prioritize products based on a list of ~1200 potential chemicals of concern. An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint.

A. Key Prioritization Factors

The proposed prioritization process creates significant uncertainties. Although DTSC has indicated its goal is to prioritize a small number of products for review, the draft does not articulate a clear, step-by-step process for doing so. The draft indicates that DTSC may rely on information developed or received under the regulation, but is not limited to such information in reaching a prioritization decision. The lack of explicit description raises questions about the nature and type of information DTSC, in fact, might use to reach a decision.

B. Aggregate & Cumulative Risks

The success of the product prioritization process hinges on the evaluation of aggregate and cumulative risks. As it is currently written, it is unclear when, how often and through what process DTSC will conduct an evaluation of a chemical's aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or perhaps both. Dow is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks from the total exposure to a specific chemical from all different sources and routes requires considerable data and information that manufacturers of individual products do not have and cannot readily obtain. Manufacturers and/or sellers of a given consumer product would need information on each individual consumer's occupational exposures, medication and diet, information that would surely raise privacy concerns.

The lack of a process not only presents a challenge of predictability for industry, but it also poses significant challenges for actual implementation. Cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. Individual companies cannot possibly know all of the possible sources and uses of any given chemical outside of their own control, thus rendering cumulative risk analysis impossible. In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

C. Weight of Evidence

The SCP regulations do not currently include any "weight of the evidence" approach for evaluating the toxicity of chemical substances and other scientific questions pertaining to human health and the environment. It is a general principle of hazard assessment that all available data must be considered and the totality of relevant and reliable information integrated in order to arrive at a scientifically-defensible decision regarding chemical hazard. These regulations do not currently have a process to evaluate credible hazard trait data in a manner that addresses the relevance, quality and significance of the data. Dow supports the integration of exposure-based traits that will allow for the prioritization of chemicals based on widely-perceived objective, scientifically-based studies that have been vetted in an open, deliberative and transparent scientific process.

D. Alternatives Analysis Exemptions

Having clearly-defined criteria for evaluating hazard traits and exposure around environmental and health concerns is integral to the success of chemicals management regulations. It appears that the approach to Alternatives Analysis Exemptions currently defined in the regulations will be arbitrary and inconsistent.

Dow supports a reasonable de minimis threshold, or alternatives analysis threshold of 0.1% (1,000 ppm). This is a threshold that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program. More importantly, it is a practical threshold that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. DTSC should limit application of the regulation to intentionally added constituent chemicals.

While Dow appreciates DTSC's attempt to establish a unique approach to threshold limits, or lack thereof, the inconsistency with other federal and international bodies will create an unnecessary level of confusion for implementation. What criteria will DTSC use to trigger the need to establish a different de minimis level? Also, what standards will be used to evaluate the "available information" to warrant a higher or lower level? Dow recommends that DTSC carefully consider clarifying the process for establishing Alternatives Analysis Exemptions.

E. Minimum Detectable Concentration

The initial intent of the SCP regulations focused on minimizing potential exposure to COCs while spurring the innovation needed to select safer consumer products. Unfortunately, the current regulations are focused less on safe use and more on product deselection. Draft language indicates that DTSC will defer to the "minimum detectable concentration" level for the COC in the product. Dow is concerned that reliance on the limit of detection, in conjunction with precautionary language such as may "contribute to" adverse public health and environmental effects, and, deference to regulatory responses that provide the greatest level of "inherent protection," is establishing a framework focused on chemical elimination rather than safe use. A minimum detectable concentration cannot function as an exemption threshold, nor can it be used to document incremental improvement.

III. Alternatives Analysis

The second stage of the alternatives assessment focuses on the comparison of alternatives. However, the criteria for determining a "demonstrable contribution" or a "demonstrable difference" are unclear. DTSC should define the process that will be used to evaluate factors relevant to the comparison of Priority Products and the alternatives. Dow would support the use of quantitative analysis tools like QSAR models to facilitate the comparison. These types of quantitative tools will help identify situations where there are other categories for which the alternatives are no better and possibly worse for potential toxicity or environmental hazards. Conducting comparative analysis under this rubric allows DTSC to conduct a more comprehensive review instead of merely relying on available qualitative information. Reliance on existing available information in this context presents a challenge because two purportedly "reliable" sources may not yield the

same results or enjoy the same level of scientific standing. Dow recommends the use of quantitative tools that will enhance comparative assessment around exposure potential for consumer products.

IV. Duplication of Worker Exposure Standards

The overarching intent of the Safer Consumer Products regulations is to focus on exposure risks associated with consumer products. Thus, focusing on workers exposure in a retail setting seems to be an appropriate consideration for these regulations. Dow strongly believes that the scope of these regulations should focus on conventional consumer products in retail settings. There are OSHA exposure standards already in place for worker safety in industrial settings, and it would be unnecessary and duplicative for DTSC to appropriate its very limited resources in this manner. As just one of many examples, it seems reasonable to assume that the statute did not intend to contemplate additional regulations for an industrial worker filling railcars for shipment. Furthermore, some raw materials and intermediates may be “consumer products” under the regulations, and DTSC will have no authority to regulate the use of these materials outside of California. This creates a disincentive for California-based businesses, jobs, and operations. A manufacturer will actually be motivated to move out of state and sell back into California to avoid this duplicative regulation of the workplace. Not contemplated in this regulation is this “leakage” of jobs out of the state.

V. Confidential Business Information

The protection of confidential business information (CBI) and trade secrets are considered sacrosanct among all business partners and industry representatives. DTSC continuously references its adherence to the existing legal framework for CBI and trade secrets laws and states that these regulations will not conflict with this existing framework. However, Dow believes that DTSC’s goal of transparency may be undermined by the regulations because they compound the complexity of DTSC’s trade secret determinations. Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes. The current framework outlines excessive requirements that should be revised.

GCREgs@DTSC

From: Julie Dull <dhsproperties@gmail.com>
Sent: Thursday, October 04, 2012 8:59 AM
To: GCREgs@DTSC
Subject: Please

Please enforce this law. And make the eules strong. We are exposed to chemicals all the time and at least need to know what they can do.

Julie dull



Sent from my iPhone

Ecolab Inc.
370 N. Wabasha Street
St. Paul, Minnesota 55102-1390

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Via E-Mail GCReqs@dtsc.ca.gov and U.S. Mail

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

On behalf of Ecolab, I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

Around the world, businesses in the foodservice, food processing, hospitality, healthcare, industrial, and oil and gas markets choose Ecolab products and services to keep their environments clean and safe, operate efficiently and achieve sustainability goals. For nearly 90 years, we've worked behind the scenes to keep food safe, prevent the spread of infection and protect vital resources.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

Ecolab seeks clear administrative guidance and regulatory clarification of how DTSC will apply the Safer Consumer Product regulations to industrial product uses – e.g., cooling tower treatments, boiler treatments, wastewater applications, products used in petroleum exploration and refining, and other chemical products sold to heavy industry, and not within the common sense understanding of "consumer product."

DTSC has stated in public forums intent to not designate industrial use products as "priority products." However, the definition of "consumer product" in the Health and Safety Code indicates that industrial products in the California marketplace can be designated "priority products" at the discretion of the DTSC.

*SAFER CONSUMER PRODUCTS, Proposed Regulations, R-2011-02
(22)(A) "Consumer product" or "Product" means any of the following:
1. A "consumer product" as defined in Health and Safety Code section 25251;*

HEALTH AND SAFETY CODE SECTION 25251

25251. For purposes of this article, the following definitions shall apply: ...

(e) "Consumer product" means a product or part of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:

- (1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.
- (2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.
- (3) A device as defined in Section 4023 of the Business of Professions Code.
- (4) A food as defined in subdivision (a) of Section 109935.
- (5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).
- (6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide (7 United States Code Sections 136 and following).
- (f) This section shall become effective on January 1, 2012.

Ecolab recommends that DTSC use available administrative measures to harmonize its definition of "consumer product" (above), with the following CARB regulations, as both groups are within the Cal/EPA and multiple definitions of consumer product within an Agency create ambiguity and unnecessarily complicate business planning for products that are not within the intended scope of the regulation:

REGULATION FOR REDUCING EMISSIONS FROM CONSUMER PRODUCTS
SUBCHAPTER 8.5 CONSUMER PRODUCTS
Article 2. Consumer Products § 94508. Definitions

"Consumer Product" means a chemically formulated product used by household and institutional consumers including, but not limited to, detergents; cleaning compounds; polishes; floor finishes; cosmetics; personal care products; home, lawn, and garden products; disinfectants; sanitizers; aerosol paints; and automotive specialty products; but does not include other paint products, furniture coatings, or architectural coatings. As used in this article, the term "consumer product" shall also refer to aerosol adhesives, including aerosol adhesives used for consumer, industrial, and commercial uses.

Chemicals of Concern Identification

The proposed regulations establish general Chemicals of Concern based on 22 lists from various state, US Federal, and international government bodies. The DTSC continues to ignore the statutory mandate to identify and prioritize chemicals of concern. Ecolab seeks a prompt and clear identification of the specific chemicals of concern, including chemical abstract registry (CAS) numbers. Product development cycles that include bench scale formulation, pilot plant production, field testing, manufacturing scale-up, and channel distribution of a new product are considerably longer than the timelines described in Article 5 (Alternatives Assessments), Article 6 (Regulatory Responses), and Article 7 (Dispute Resolution Process). Companies require clarity on the prioritized chemicals of concern to enable efficient business planning required to meet the broad requirements of this regulation.

Specifically, at Section 69502.2(a): Initial Chemicals of Concern List, Ecolab recommends the initial listing focus on known carcinogens, reproductive and developmental toxicants, and the persistent, bio-accumulative and toxic (PBT) substances as defined by the US EPA. A number of the proposed lists should not be used, such as the Category 1 endocrine disruptors list at (1)(C) that has been disavowed by EU authorities, the Washington State PBT list at (1)(N) that did not use criteria consistent with the US EPA PBT list, and the non-authoritative OSPAR list at (2)(H).

Alternatives Analysis: Threshold Determination

Section 69503.5 – Alternative Analysis Threshold Exemption – Ecolab is troubled by the Department's abandonment of the simple concentration-based approach it had proposed earlier in favor of a process-based approach that will be primarily based on the minimum detectable concentration for the Chemical of Concern in a product. Moreover, we find it disturbing that the Department acknowledges that the AA threshold may well be below a level that represents an insignificant or negligible risk, too small to be of concern. It is unclear why the Department would impose such heavy regulatory burdens on companies in cases where it knows there is no opportunity to protect the public or improve environmental quality. Ecolab recommends that the Department return to its previous proposal of an administrative concentration-based AA Threshold of 0.1% and 0.01%.

Alternatively, the AA Threshold Exemption process could also be eliminated in favor of a self-assessment process. For example, OEHHA uses a self-assessment process under the Proposition 65 Safe Harbor provisions for companies to determine whether there is a need to label a product. This aspect of Prop 65 has been very successful and should be a model for the application of the de minimis provisions of the Safer Consumer Product regulations.

Reformulation of high performance, innovative products requires significant development time along with time to manage associated business issues ranging from customer contracts and notifications to managing plant and warehouse stock. The Safer Consumer Products regulation in total does not allow manufacturers adequate information to appropriately plan and prepare for compliance let alone innovation. This includes:

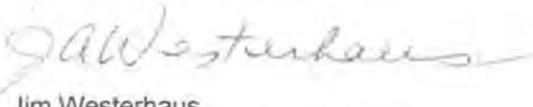
- Disclosing only a list of lists, and not a defined list of the chemicals of concern (COC)
- No clear criteria for defining Priority Product, and no transparency to details of the Priority Products in each phase
- Alternatives Analysis thresholds will be defined on a case by case basis using only loosely defined criteria.

All of these unknowns make it very difficult to prepare appropriately for compliance and business continuity, as well as to innovate. A manufacturer is left to choose to act based on the best guess around COC and Priority Products, or to wait until the details are issued. We understand that the intent of these regulations is to minimize the potential for exposure to hazardous chemicals of concern, and to encourage the innovation of safer products. Understanding this intent, we are concerned that the proposed approach creates an unpredictable framework, increasing uncertainty, and will not allow sufficient development time for truly innovative solutions. Additionally, the current draft of the proposal threatens intellectual property, upon which innovation is founded.

To facilitate the Alternatives Analysis process, to reiterate, we recommend that the Department return to its previous proposal of an administrative concentration based AA threshold of 0.1% and 0.01%. A process-based approach should be self-implementing and risk-based. A more focused program could concentrate on the substances in products that pose true risks for human health and the environment, based on exposure, hazard and the likelihood of harm. We believe that, no Proposition 65 chemical should have an AA Threshold below the No Significant Risk Levels (NSRLs) for cancer-causing chemicals or the Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity.

Thank you for consideration of our concerns.

Sincerely,



Jim Westerhaus
Government Relations Vice President

cc: Larry Berger, Jim Seifert, Steve Christenson, Bill Phillips, Lynne Olson

Electronics Industry Comments on Proposed Regulation on Safer Consumer Products (July 2012)

The Information Technology Industry Council (ITI), TechAmerica, the Consumer Electronics Association (CEA) and the Semiconductor Industry Association (SIA), are pleased to provide these comments on behalf of the information technology, consumer electronics, and semiconductor industries on the Proposed Regulation for Safer Consumer Products (Proposed Regulation). We appreciate the opportunity to provide input on the Proposed Regulation and we look forward to working with the California Department of Toxic Substances Control (DTSC) as the Regulation is finalized and implemented.

Our member companies have long been leaders in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design, energy efficiency and product stewardship. ITI, TechAmerica, CEA and SIA are submitting these comments in order to promote the development of consumer product regulations that will expand on the environmental efforts of our member companies and drive improvements in environmental performance and ensure California's continued leadership in technological innovation.

General Comments:

We offer specific comments on sections of the Proposed Regulation below, but wish to offer several overarching comments. As we have mentioned in our previous comments, when AB 1879 was signed into law by then Governor Schwarzenegger, Governor Schwarzenegger specifically noted that AB 1879 and its implementing regulation were to draw on "lessons learned" in other jurisdictions, and take into account programs in other states, countries and regions, such as the European Union, and build upon their experience, data and expertise.

Unfortunately, it does not appear that the Proposed Regulation was developed with the perspective of learning from other jurisdictions' experience in developing chemical regulations. In previous comments, we have provided several examples of how such experience and expertise can be used to improve the Proposed Regulation; however, we have seen little improvement in this area. We suggest that the DTSC consider how other jurisdictions regulate chemicals used in consumer products when redrafting these regulations.

Overall, the electronics industry considers the Proposed Regulation to be an improvement over the informal draft regulations that were released in 2011, but we still have significant concerns with the Proposed Regulation. The Proposed Regulation presents a very onerous and potentially costly regulatory scheme that is predicated on significant paperwork requirements, for both industry and the DTSC, and an overreliance on testing that, especially for manufactured products (e.g., articles), will be difficult and expensive, while providing few, if any, environmental benefits.

The electronics industry is concerned that the Proposed Regulation is overly subjective and needs to be more focused on objective and standardized processes. It is critical that any person doing a regulatory analysis or determination under these regulations will be able to reach a similar conclusion. Currently, the Proposed Regulation is overly deferential to the DTSC and too discretionary in several areas, mostly but not exclusively in the prioritization and regulatory response areas, for which we've provided specific comments.

While we appreciate that the DTSC is looking for flexibility to allow for changes in science and in response to new information in chemicals management, in many cases, the overly-flexible language only provides ambiguity, does little to provide the regulated community with regulatory certainty, and could provide a disincentive to voluntary actions in the marketplace. While the DTSC has recently assured industry that the regulatory assessment process will be consistent across individual cases, future administrations may take different approaches if given the regulatory authority to do so. We suggest that, in particular, the DTSC provide clear processes for prioritization and clear triggers for regulatory actions. There should also be a provision allowing for the regulations to be revisited if there are changes in the scientific or economic landscape.

The electronics industry suggests removing the term "homogenous material" from the Draft Regulations, but retaining the concept and intent of targeting specific materials within a larger consumer product by modifying the definitions of "component" and "consumer product." While we agree with the intent of regulating specific uses of a material in certain and clearly defined cases, the term "homogenous material" has been problematic, even the improved version that is contained in the European Union's revised RoHS Directive (termed "RoHS Recast")¹. In our comments, we suggest that, by modifying the definitions of "component" and "consumer product," the DTSC will have the ability to target chemicals of concern in specific materials, but will not propagate a still problematic definition contained in another regulatory program.

We believe that several provisions contained in the Proposed Regulation, especially those requiring testing, may constitute a technical barrier to trade) under the World Trade Organization's Agreement on Technical Barriers to Trade². When suggesting restrictions on the use of any chemicals, the DTSC must be able to list acceptable, internationally-recognized testing methods that will allow manufacturers to demonstrate compliance with the regulatory requirements. However, testing should not be viewed as the only means of demonstrating compliance as there are often less costly and destructive means to determine regulatory compliance, such as supply chain disclosures and material declarations.

The electronics industry continues to oppose the use of Certified Assessors in Article 8. We provide more detailed comments on this Article below, but we believe that the use of Certified Assessors will not provide any certainty to the DTSC, public or manufacturers that the assessment has been done correctly and thoroughly, and can, in fact, raise significant legal issues for the Assessors, the manufacturers and the DTSC. The use of a Certified Assessor, with DTSC review and acceptance of the

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF>

² <http://www.worldtradelaw.net/uragreements/tbtgreement.pdf>

Alternatives Assessment (AA) results, raises a basic question up for debate as to who is ultimately responsible, and subsequently liable, for the selection of materials in a product. We have stated repeatedly in previous comments that an AA is only one data point of several that inform the decision of which materials are selected for use in a product. We believe that the DTSC is erroneous in assuming that there will be a clear “winner” material in an AA that should be used above all others. It is rarely the case that an assessment will provide an overwhelmingly clear answer.

Finally, the Proposed Regulation raises several concerns related to trade secret and confidential business information (CBI) protections. In several parts of the Proposed Regulation, requirements are established that would require manufacturers to supply information to the DTSC, such as specific information related to sales and manufacturing processes, which are often closely-held, private business information. ITI, TechAmerica, CEA and SIA recommend that the DTSC review the information that is being requested and consider the potential trade and business ramifications of divulging such information. We make specific comments on this important issue in our review of specific sections of the Proposed Regulation below.

Specific Comments by Section:

Article 1. General

Section 69501.2 Definitions

“Homogenous Material” – Because of the difficulty with the term “homogenous material” we suggest removing this definition (part 34) from the regulations in its entirety. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but as mentioned previously, the definition of “homogenous material” is not viewed as well defined in the EU RoHS Directive by all stakeholders, and attempting to harmonize with a term that is problematic to some in the industry will make compliance difficult for both the Department and manufacturers.

Additionally, while we support the continued exclusion of “Historic products” from the definition of “Consumer product” and therefore from being subject to these regulations, we note that the proposed definition fails to include any necessary repair or replacement parts to maintain such products. The continued manufacture and availability of repair and replacement parts without being subject to these regulations is critical to maintaining the cost-effective support and operation of these products for our customers. As noted in the Initial Statement of Reasons (ISOR), the definition of “manufacture” (40) is intended to also exclude “replacement parts” as may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference replacement parts. We recommend below that these definitions be modified accordingly.

Thus, we recommend that the definitions of “Component” and “Consumer Product” be changed to read:

(21) “Component” means a uniquely identifiable part, piece, assembly, subassembly or uniquely identifiable material within a single part, piece, assembly, subassembly of a consumer product that:

- (A) Is required to complete or finish an item
- (B) Performs a distinctive or necessary function in the operation of a product or part of a product
- (C) Is intended to be included as a part of a finished item

(22)(A) “Consumer product” or “Product” means the following:

1. A “consumer product,” including component, as defined in Health and Safety Code section 25251, that is identified under section 69503.4(a)(2)(B), as the minimum required focus of an AA.

(B)1. “Consumer product” or “Product” does not mean any historic product.

2. “Historic product” means a product that ceased to be manufactured prior to the date the product is listed as a Priority Product, and includes its service, replacement and repair parts regardless of when manufactured that are necessary to maintain and/or repair the historic product.

(C) “Consumer product” or “Product” does not mean a product previously owned or leased by someone other than the manufacturer, importer, distributor, or retailer of the product.

(40) “Manufacture” means to make, produce, or assemble. “Manufacture” does not include any of the following actions, unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:

(A) Repair or refurbishment of an existing consumer product, including the manufacture of repair or replacement parts;

(B) Installation of standardized components to an existing consumer product; or

(C) Making non-material alterations to an existing consumer product.

Additional definitional recommendations:

(26) “End-of-life” – This definition would encompass stages of a product life cycle where products may be reused or refurbished and, therefore, are not considered to be at their “end-of-life.” This is an important distinction for electronic products. We suggest tying the end-of-life to when a product enters the waste stream and no longer has useful life.

We believe that DTSC could address this concern by changing the definition of (26) to read:

(26) “End-of-life” means the point when the product is at the end of its useful life, and is discarded for recycling or disposal by the consumer.

(52) “Reliable information” – We are concerned that the definition of “reliable information” assumes that too much information is *de facto* deemed “reliable” simply because it has been published in peer reviewed journals or by state regulators. We believe neither of these scenarios automatically make information “reliable” We recommend that, due to the limitations of peer review³ and state agency reports, that a process for disputing the reliability of such information be included. .

³ See OMB’s Information Quality Guidelines, 67 Fed. Reg. 8452, 8455 (Feb. 22, 2002).

Recommendation:

We suggest revising the definition of “Reliable information” to read as follows:

(52) (A) “Reliable information” means a scientific study or other information that is one or more of the following:

1. Published in a scientifically peer reviewed report or other literature;
2. Published in a report of the United States National Academies;
3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
4. Conducted, developed, submitted, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

(B) Interested parties may dispute the information from the Department in public workshops or during comment periods.

Section 69501.2. Duty to Comply and Consequences of Non-Compliance

(a) Duty to Comply.

Subpart (a)(2) should allow a consortium, trade association, public-private partnership, or other to apply for technology-specific exemptions under sections 69503.6 and 69503.7, rather than each company being required to do so independently. Thus, to minimize the compliance burden on individual companies, we recommend the following:

Change subpart (a)(2) to read:

The requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity.

(b) Manufacturer and Importer Options.

(b)(1) and (2) - These notification requirements will only serve to burden manufacturers and the Department, with no discernible benefit to the environment, and (b)(2) will significantly increase the burden of placing new products on the market. The Department has consistently stated that the regulations must reward innovation. However, these requirements will significantly slow the introduction of new products in the California market.

We believe one way that DTSC could address this concern is as follows:

Change subpart (b) (1) and (2) to read:

if a priority product is either removed from commerce in California, or if the product has been redesigned to remove or reduce the chemical(s) that were the basis of an AA or replaced, the

manufacturer must be able to demonstrate to the Department's satisfaction, upon request, that the product has been removed from commerce or redesigned or replaced in the marketplace.

A similarly simplified process should also be applied to the Retailer Option under subpart (c).

Section 69501.4. Chemical and Product Information

The Department should not request information from responsible parties unless publically-available sources of information have been exhausted. We suggest that the Department specify that the approaches outlined are in order of preference.

It is not clear how the Department will handle cases where responsible parties do not have the information being requested or if there is conflicting information between sources of information; in particular for information submitted by responsible parties.

Article 2. Chemicals of Concern Identification Process

Section 69502.2. Chemicals of Concern Identification

While we appreciate that the lists presented in the regulation have been pared down from previous versions, the list of chemicals identified by the list of lists in § 69502.1 will still be in excess of 1,000 chemicals. We are concerned that the purpose of this list will be misconstrued by companies in the supply chain as well as by governments, NGOs, and in particular by members of the general public whose lack of understanding with this complex regulation may lead to unfounded fear. It is very likely that the chemicals identified by this process will have a stigma attached to them that will cause their use to be unnecessarily challenged or questioned, even though the chemicals may have already undergone an assessment or have been determined to be safe in specific applications. The electronics industry believes that the approach suggested by Mr. Mike Rossi of the Governor's office is appropriate for the chemicals of concern identification process, which is reflected in our recommendation below.

Further, we believe that there should be different terms to address specific instances in the regulation. The term "Chemical of Concern" (CoC) currently means a chemical on the list per section 69502.2 that exhibits a hazard trait; the chemical paired with a specific product and the focus of the alternatives assessment in sections 69503.4 and 69503.5; and could mean any chemical requiring reporting to the Department in section 69505.5 or disclosure in consumer information in section 69506.4. Using different terms in different instances will clarify what the Department is referring to at any part in the regulatory process.

Recommendation:

The electronics industry recommends a two-part process for identifying chemicals of concern. First, a list of "Chemicals of Interest" are developed using the process in Section 69502.2, then a pared-down

“Chemicals of Concern” list is developed from the “Chemicals of Interest list” and specific factors identified by the Department. Finally, a “Priority Chemical” is a chemical that has been paired with a priority product and is the focus of the Alternative Analysis. This Priority Chemical will also be the focus of any regulatory actions that stem from the AA.

Article 3. Chemicals of Concern and Consumer Product Prioritization Process

Section 69503.1. Applicability

The Statement of Reasons document for these regulations is very clear that products that do not contain a chemical of concern are not subject to the requirements of this Chapter. However, the regulations are not as clear on this point.

Recommendation:

There are two options that we believe address this concern.

Option 1 - Add a second sentence:

This section is not applicable to products that do not contain one or more chemicals of concern.

Option 2 – Modify the definition of Priority Product:

(48) “Priority Product” means a product containing one or more Chemical(s) of Concern as identified and listed as a Priority Product by the Department under section 69503.4.

Section 69503.2. Priority Products Prioritization Factors

The regulations have several factors that include the concept of exposure, but exposure of a chemical of concern is not a factor in the prioritization. While the regulations do contain subpart (a)(1)(B), the regulations seem to assume that any exposure to a product equates to exposure to the chemical of concern, so this subpart relates to exposure to the product, not to the chemical of concern.

“Containment of the Chemical” within the product is included in the product prioritization criteria in subpart (a)(1)(B). As described in the ISOR, “how the Chemical of Concern is contained or bound during the use of the product determines, in part, the amount of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user, in which case, there is little to no exposure as a result of use of the product.” These are meaningful and practical ways to assess exposure to a chemical in a complex product or article and should be retained. We suggest that the Department add language in subpart (a)(1)(B) to clarify that “containment” includes the concept of accessibility as described in the ISOR. “Accessibility” is a commonly-accepted term with

well-established tests for whether a part of a product is accessible or not for chemical exposure purposes, such as the test used by the Federal Consumer Product Safety Commission.⁴

Finally, subpart (a)(1)(B)(4)(a) discusses chemical exposures during manufacturing. The Department has been consistent in stating that these regulations cover consumer products and chemicals. Exposures during manufacturing processes are already covered under existing authority by the federal Occupational Safety and Health Act (OSHA), and should not be included in these regulations.

Recommendation:

We recommend that this section, in particular subpart (a)(1)(A), be greatly simplified and specifically mention exposure as a factor. One way that DTSC could address this concern is as follows:

Change (a)(1) to read:

Adverse impacts and exposure. The Department will consider the adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to the physicochemical properties, environmental fate, hazard traits and the possibility and likelihood of exposure to the Chemical(s) of Concern through reasonably foreseeable use and abuse of the product.

Additionally, we believe further clarity could be provided by the following:

Change (a)(1)(B)(4)(d) to read:

Containment of the Chemical(s) of Concern within the product, which includes whether the Chemical(s) of Concern is in an inaccessible component within a product.

Subpart (a)(3) also has the Department “considering” other California and federal laws. The electronics industry strongly believes that, as in previous drafts of the regulations, devices that are already regulated for a particular chemical use must be exempt from these regulations. The potential for multiple, conflicting and confusing regulatory schemes is too great to simply make those a factor for consideration. At the least, there should be considerations for exempting products that are previously regulated under other international or federal chemical regulatory regimes. There should be a presumption that chemical risks have already been reduced in such cases.

Subpart (b) lists key prioritization factors the Department will consider. We believe this process is more complicated than in previous drafts, and suggest the Department consider expanding these key criteria to make it clearer when a product may meet them.

⁴ <http://www.cpsc.gov/about/cpsia/inaccessiblefr.pdf>

Recommendations:

We suggest the Department give priority to products meeting the following criteria:

- (1) The chemical of concern in the product have a significant potential to cause adverse public health or environmental impacts;
- (2) The product is widely distributed in commerce and widely used by consumers;
- (3) There is significant potential for public and environmental exposures to the chemical(s) of concern in the product in quantities that can result in adverse public health or environmental impacts; and
- (4) For assembled products, the product contains one or more chemicals of concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts during intended and reasonably foreseeable use.

Section 69503.3. Process to Evaluate Products Using the Prioritization Factors

While this section is labeled a process, the electronics industry does not believe this is truly a process as required by AB 1879. As we mention in our general comments on the regulations, we are concerned that any person, or any administration, conducting this process will not generate similar results. While we appreciate that different entities (i.e., manufacturers vs. regulators) will have different assumptions and potentially different expertise, the process should still be sufficiently standardized so that anyone who does the process in good faith will come up with a similar result. We are not convinced that this is the case with the SCP regulations. There is simply too much discretion and variation in the steps enumerated in this section.

We recommend that the DTSC revert to the flow chart process that the DTSC used previously. A flow chart approach or, at least, a step-wise approach will be more systematic and less subjective than the current proposal.

Subpart (f)(1)(B) allows the Governor's office to potentially skip all of the Article 2 Chemical of Concern identification, and to unilaterally give priority to a chemical without any process or public input. While the final list would be open for public comment, it would be too late in the process to respond to any potential issues stemming from a Governor's Executive Order. We believe this is too broad a mandate and needs to be either removed or moved to the CoC identification in 69502.2.

Section 69503.4. Priority Products List

Subpart (a)(2)(B) introduces the concept of the highly durable product. While we appreciate the intent of this term, we are not sure that it will adequately distinguish between formulated products and articles, and we believe that the limits placed on the department for selection of components and materials (10 per product every 3 years) are not useful. Alternatives assessments on articles are often very long and complex undertakings. For example, the US EPA Design for Environment program has been investigating alternatives for decaBDE in plastic casings. This assessment has taken over 3 years

and has consumed several hundred thousand dollars, and has just gone out for public comment. While we recognize that this case is more complex than many others, it is still not unusual for assessments on electronic products to take two – three years. Having a limit of 10 things every three years will still potentially have manufacturers in a constant loop of mandated assessments.

Subpart (d) notes that the Department may respond to some or all public comments. We believe that for a truly credible process, the Department has the obligation to respond to all public comments. We do recognize that the response will be, in some cases, that a comment is without merit.

(a)(2)(B) – Per our comments on homogenous material in Section 69501.1, we recommend changing (B) to read:

(B)1. If applicable, the component(s) and/or uniquely identifiable material(s) within a component, to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA.

2. For each Priority Product that is a highly durable product, the Department shall in all cases specify the number of component(s) and/or uniquely identifiable material(s) within a component to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA. For each listed highly durable product, the Department shall specify no more than ten (10) components and/or uniquely identifiable materials per product every three (3) years.

Section 69503.5. Alternatives Analysis Threshold Exemption

As mentioned in comments to previous Draft Regulations, we believe that the inclusion of cumulative concentrations (in subpart (d)) will add ambiguity to the regulations that will make it very difficult for the Department and manufacturers to determine compliance with these regulations. For example, if a chemical gets reclassified or a new chemical of concern gets added to an existing priority product, then industry and DTSC personnel will have to re-calculate all the existing threshold level summations as the grouping of chemicals subject to the threshold will change. Further, manufacturers will not be able to use existing data and compliance systems, which are all based on single chemical thresholds, to ensure compliance with these regulations. This will delay DTSC's ability to quickly and efficiently implement the new regulation as both industry and the agency will be required to develop innovative new business processes and/or software tools that are capable of calculating the summation of chemicals vs. applying the threshold to a single chemical. This will divert valuable agency resources to focus on documenting that chemicals are not present in products from the primary purpose of the regulation which is to identify safer consumer products.

Finally, it is not always possible to analytically quantify all chemicals in a consumer product, especially for assembled products which may have matrix interferences, or some inorganic compounds with only analytical methods for the elements but not the full chemical compound. Therefore, having the threshold potentially set at a cumulative sum of chemicals and not an individual chemical increases the complexity of quantification to a sum total as more and more chemicals may fall into the category of "unquantifiable." As the department adds more chemicals to a priority product, the cumulative sum threshold will become more and more difficult to quantify as the thresholds get smaller and smaller

going below any ability of analytical detection limits. This uncertainty will be exacerbated in more complex assembled products and will only make the compliance demonstration and/or enforcement more difficult.

The electronics industry acknowledges the importance of considering cumulative chemical effects, however, we believe this should be considered during the product prioritization phase and can be addressed through regulatory responses, but it is not appropriate for a threshold determination.

Section 69503.6. Alternatives Analysis Threshold Exemption Notifications

The electronics industry continues to believe that these minimum threshold exemptions should be self-implementing. The amount of information being requested by the Department to demonstrate that the levels are below that which should be regulated will be overwhelming to the regulated community and the Department. Additionally, there is a dependence on testing results to “prove the negative” that a chemical is not in a product, where a compliance assurance system, which may include but does not require testing results, is in most cases much more practical for manufacturers to manage the content of their products and the Department to ensure compliance with the regulations.

Recommendations:

The electronics industry suggests that much of § 69503.6 be deleted, and replace with a compliance assurance process where the Department may request information from the manufacturer.

In creating a program to ensure compliance with the threshold exemption, the Department should remove the implication at § 69503.6(a)(5) and (a)(7) that only analytical testing results are appropriate substantiation that a product meets the threshold exemption. Given the sheer number of chemicals of concern based on regulations and customer restricted/banned substances lists, testing for all of these chemicals is cost-prohibitive. Therefore, manufacturers commonly rely on supplier certifications regarding purchased material content to understand product ingredients and impurities, and cannot routinely test all purchased materials or finished goods. Responsible manufacturers augment supplier information with testing when knowledge of the chemistry of the product indicates probable presence of chemicals of interest, or when there is cause to doubt the veracity of the supplier certification. This method has been widely used to determine compliance with international chemical restriction laws and regulations and is sufficiently rigorous and credible to provide a model for the Safer Consumer Products Regulation.

Section 69503.7. Priority Product Notifications

As written, this section will inundate the Department with information as soon as a Priority Product list is published. The Department should reconsider the reporting and notification requirements in the regulations, considering the burden on the manufactures to produce this information and the Department to receive process and respond to it. It is not clear why the Department would need all of the information requested, in particular all of the information in subpart (a)(2).

Article 4. Petition Process for Identification and Prioritization of Chemicals and Products

Section 69504. Applicability and Petition Contents

We are concerned that the requirement of subpart (b), that a chemical be off all lists, is an overly high hurdle to clear to request a petition. The lists in section 69502.2(a) are all updated on different cycles, with some taking significantly longer than others to refresh. If there is significant new information, it is unlikely that it will change all of the lists within a reasonable time frame. The section should allow petitioners to remove Chemicals of Concern on a showing of “preponderance of the evidence” that the scientific evidence supports removal.

Recommendation:

We believe one way that DTSC could address this concern is as follows:

(b) Change to read:

A person may not petition the Department to delist any chemical identified as a Chemical of Concern unless that chemical has been removed from at least one list identified in section 69502.2(a).

Section 69504.1. Merits Review of Petitions

This section contains a list of factors the Department will consider in making a determination of whether a petition will be denied or granted. However, the criteria listed are only applicable to petitions to add substances to the Chemical of Concern list. There should be factors for how a chemical may be petitioned for removal from the CoC list.

Further, we are concerned with the subjectivity of this section. As with previous sections, there should be assurances that the petitions will be reviewed with a process that is dependent only on the science and merits of the review. We suggest that the Department develop a process or explanation of how the factors will be applied so that petitions may be reviewed more consistently based on an objective determination.

Article 5. Alternatives Analysis

Section 69505. Guidance Materials

The electronics industry contends that not all methodologies to perform an assessment are of equal caliber. Therefore, we are concerned that a process that has less rigor than necessary may be promoted and accepted as guidance by the department, and processes that are applicable to one type of products but not others may be used by assessors that do not understand the products and how they are produced. Therefore, we suggest that the Department allow for public input into the guidance materials when they are posted.

Section 69505.1. Alternatives Assessments: General Provisions

As mentioned in our general comments, the electronics industry feels that several of the timelines presented in the Proposed Regulations are too short to be workable. We believe that subpart (b)(3)(C) is an example of this. Some of our associations' member companies have done assessments using the guidance in previous drafts of the regulations, and the preliminary steps took longer than 180 days. For simpler products, it is possible that a shorter timeframe is practical, but for high tech products with a complex supply chain, 180 days is too little. We suggest allowing the Department to set due dates when the Priority Products List is published. Allowing flexibility for the due dates may provide manufacturers with the opportunity to work with their supply chain and develop meaningful AAs.

As we mention in our comments to Article 8, we believe the requirements for a Certified Assessor in subpart (e) should be removed. Notwithstanding our objection to the use of Certified Assessors, we further believe that the 2 year implementation is unworkable. If the department proceeds with a Certified Assessor program, the timeframe of 2 years from the effective date of the regulations is unworkable. For the first set of priority products, a manufacturer will start the AA before 2 years is over, but may not have been able to complete it. These manufacturers should not have to switch assessors mid-stream. The DTSC should instead allow that the AA's for the first round of priority products do not require a Certified Assessor.

Subpart (g) requires that manufacturers who reformulate their products submit significant information to show that the chemical of concern is no longer in the product. We believe that this is another example of an overly-burdensome and large information request that manufacturers will be required to prepare and the DTSC will be required to process with little or no benefit to the environment. We believe that as with the AA threshold, if the manufacturer reformulates the product, no further reporting should be due. If the DTSC does feel some notice is necessary, a simple notification with the contact information and a statement that the product no longer contains a chemical of concern should be adequate. As we have mentioned previously, it is impossible to "prove the negative" that a chemical is not present, and the regulations are overly reliant on product testing to demonstrate compliance. There are many examples of other reliable and credible ways to demonstrate conformance, including supply chain declarations and internal process controls. If the DTSC is going to require testing to demonstrate compliance, it is incumbent on the Department to specify which tests are acceptable to show compliance.

Section 69505.2. Analysis of Priority Products and Alternatives

Subpart (b) notes that a responsible entity may submit an abridged AA report if an acceptable alternative is not "available or feasible." However, the Department does not specify thresholds for these terms. The Department should provide some guidance for feasibility in this section or in section 69505.3. Additionally, subpart (b) indicates that a responsible entity cannot do an Abridged AA Report without first doing a full Stage 1 study. We believe that a responsible entity should be able to do an Abridged AA Report without first going through the process of a full Stage 1 study if they rely on information from other regulatory entities or trusted bodies to show that there are no viable alternatives.

Additionally, it is not clear how the Department will approve research and development (R&D) plans under this part and section 69505.3. It is unlikely that the Department will have the industry-specific expertise necessary to adequately review and approve R&D plans.

Subpart (d) allows for a responsible entity (manufacturer) to select a different alternative from the one identified in the Final AA Report. As we note in our general comments, this may raise the question of who is responsible for the material content of a product. It is not clear who will be ultimately responsible for a product material content if a manufacturer disagrees with the Certified Assessor. This subpart allows the manufacturer to assume that responsibility, but it is not clear why they may want to do this if a Certified Assessor has already made a recommendation.

Additionally, subpart (d)(1)(B) notes that the revised Final AA Report must be submitted to the Department 60 days prior to placing the product in the stream of commerce. What is the responsibility of the manufacturer if the proposed selected alternative is already in the stream of commerce?

Section 69505.3. Alternatives Analysis: First Stage

Subpart (a) is an example of our comments in Section 69502.2, where different terms are needed to identify chemicals at different parts in the process. Using the same term depending on when referenced in the regulations is confusing. We recommend developing separate terms for these concepts in the regulation.

Subpart (b)(1)(A) notes the responsible entity must identify all legal requirements associated with the use of the product. However, the manufacturer is not likely to have this information. The manufacturers will have all compliance information for the manufacture of the product. We believe that this is what the DTSC is asking for in this section, but it should be made clear.

Subpart (b)(2)(A)1 states that alternatives must “eliminate or reduce the concentration” of the chemicals of concern in the product, but does not provide any threshold for this. As written, a trivial reduction of the CoC in the product through any means would meet this requirement. We suggest using the term “reduction in use” of the chemical of concern which will remove much of the ambiguity with the term.

The electronics industry is concerned with the requirement in (b)(2)(A)2 that a manufacturer shall consider alternatives posted for consideration by the Department. It is possible that a manufacturer has already considered these alternatives and should not be subject to doing so again, or based on the technical expertise of the manufacturer, they may be able to reject an alternative without the need for a full assessment. We suggest that the Department should not suggest alternatives, allowing the manufacturer to perform the AA, however, the Department could require the manufacturer to review and potentially explain why an alternative presented by the Department is not viable, but to require them to consider these in their AA is overly prescriptive.

Section 69505.4. Alternatives Analysis Second Stage

In subpart (a)(2), the Department assigns all responsibility for collecting and using available information and tools on the responsible entity; however, as we have pointed out, a third-party Certified Assessor may actually be the entity performing the assessment, and the Department has reserved the right to agree or disagree with the assessment results. As we have mentioned several times, this can potentially pose a significant conflict, and it is not clear who is ultimately responsible for the results of the AA. It is possible that the Department or Certified Assessor may second guess the manufacturer (responsible entity) and it is not clear what recourse, if any, the manufacturer has in these cases.

The electronics industry is concerned that the economic impacts in subpart (a)(2)(C) do not include research and development costs of using new materials, as well as performance and other testing (for example, for medical devices). These costs are important factors and should be part of the AA. Further, the Factors in subparts (B) and (C) do not include performance of the selected alternative.

Step 2 (subpart (b)) will require the use of the tools and guidance materials identified in section 69505. It is important to realize that these tools will provide important information, but will not be conclusive regarding the final decision or assessment. Weighting of the factors involved will have a significant effect on the outcome, and only the technical expertise of the manufacturer and assessor will be able to adequately weigh factors in the assessment. As we mentioned previously, there will rarely be a clear-cut “winner” material in this process, and only, after reviewing all the evidence, will the assessors and manufacturers be able to make a final decision based on the totality of the evidence. While the manufacturers will attempt to provide justification to the Department, it is not clear that the Department will agree with this justification, or for that matter, the outcome of the assessment.

Subpart (d), considering additional information, should be performed before an alternative is selected (currently subpart (c)).

The timelines for implementation of the alternative (in several sections, but mostly section 69505.5), are very tight and manufacturers, in many cases, may not be able to implement an alternative in proposed timeframe. For example, communications and medical devices have, on average, a four-year cycle between when a product is first designed to when it is formulated, assembled, and tested for performance and compliance with existing regulations. Further, smaller companies often do not have the “pull” to affect changes in the supply chain; in fact, large companies (our associations represent many of the world’s leading high-tech companies, as well as smaller or medium enterprises) often have trouble affecting changes in the supply chain since many companies are located overseas. This may lead to an outcome where certain globally-available products will not be available for sale in the State of California.

Section 69505.5. Alternatives Analysis Reports

(a) – The term “sufficient information” is used several times in this section, but is not defined in the regulations. It is not clear how the responsible entity can provide information for an appropriate due date. Section 69505.4(e) states that a responsible entity shall propose regulatory responses as part of the AA, then section 69505.5(a)(4) states that the Department will determine an appropriate regulatory

response. What is the process if the Department disagrees with the Certified Assessor/Responsible Entity proposed response?

(d) – It is very likely that the manufacturer will not have much of this information, and it is unclear why this information would be necessary for an environmental, health and safety alternatives assessment. Manufacturers typically sell to distributors or distribution centers, and they determine what products go where. Additionally, much of this information, especially the supply chain and manufacturing locations, is likely classified as “trade secret” information.

Recommendation:

Remove these reporting requirements from this section. If this information is necessary, the Department can obtain it in the process outlined in § 69506.9.

(f) – The Regulation should not dictate how information is presented in the Alternatives Analysis Reports. It is not possible, in all cases, to present a matrix or even an easily-understood visual comparison. Very complex AAs may not lend themselves to one particular type of information format.

Recommendation:

Simplify section (f) and remove most requirements for how information is to be presented. The Department should consider adding a subpart asking for clarification on a section of the AA, rather than simply asking for more information.

(g) – As mentioned in several sections, determining the relevant comparison factors is a somewhat subjective exercise and depends greatly on technical expertise and knowledge of the industry being assessed. It is not clear what will happen if the Department disagrees with the weighing and comparison of the factors.

(j) – The list of all chemical ingredients is not always available for complex parts and products, or it may be confidential information not available to the responsible party or not relevant to the AA. The further information (subparts 1-6) is potentially a significant amount of information for the manufacturer to prepare and Department to process, which may not be relevant to the AA for the chemical-product pairings. We recommend simplifying this section and paring the information required to the chemical/product information used in the AA and relied upon to make the final assessment.

(k) – As per our general and subsequent comments, it may take several years to complete these sections, and it is not clear that the deadlines in this section are practical. We recommend providing more flexibility, especially for more complex products.

Section 69505.6. Department Review and Determinations for AA Reports

It would seem that this section obviates the need for Certified Assessors in Article 8. If the Department is reviewing all AAs to ensure compliance with this section, it is not clear what role the Certified Assessor will serve in assuring the quality and thoroughness of the AAs.

Article 6. Regulatory Responses

Section 69506. Regulatory Response Selection Principles

As written, this section does not require the Department to consider the five factors listed in subsection (c) when determining which regulatory response may be appropriate, if any. Rather, DTSC is only required to give preference to regulatory responses that provide the greatest level of “inherent protection.” However, less inherent toxicity in a product should not be the only factor DTSC considers; there are many other factors involved when a decision is made to use a particular chemical in a product. Thus, DTSC should be required to consider all five factors listed in subsection (c) by eliminating the permissive language on Page 52, Line 15 and replacing it with “...the Department shall consider all of the following factors.” We believe that reasonable consideration of all five factors prior to imposing any regulatory response will be critical if the program is to be practical, meaningful, and legally defensible. Additionally, the Department should consider existing regulations when determining a regulatory response.

Recommendation:

Add the following line to subpart (c):

(c)(6) Existing regulations for that product

Finally, while we appreciate that DTSC has included a cost-effectiveness consideration in (c)(2), we are concerned that the Department will not have the information necessary to do an effective cost-benefit analysis of the regulatory response.

Section 69506.1. Applicability and Determination Process

We believe that this section should include a minimum timeline for when a regulatory response will be required to be implemented. Given the complexity and significance of the regulatory response options at the Department’s disposal, we believe that regulated entities should be given a minimum of one year after the receipt of the final regulatory response determination notice to implement the regulatory response. This timeline should increase depending on the severity of the regulatory response selected.

Section 69506.2. AA Report Supplemental Information Requirements

As written, we believe that this regulatory response would act as an overly broad and unnecessary mandate on companies, giving the Department the ability to demand any information from a company on any timeline it chooses. We suggest the following changes:

§ 69506.2 (a) – Change to read:

(a) The Department may require a responsible entity to provide, within a reasonable time frame specified by the Department, information supplementary to the Final AA Report...

§ 69506.2 (b) – Change to read:

(b) The Department may require a responsible entity to obtain or develop, within a reasonable time frame specified by the Department, information that is reasonably attainable by the entity to fill one or more information gaps identified in the Final AA Report...

In addition to these changes, we believe that the information demands made by DTSC should be targeted and reasonable, rather than overly broad. Furthermore, once the required information has been provided, that action should fulfill the regulatory response obligation for a reasonable period of time, so that a compliant entity is not continuously required to generate more and more information.

Section 69506.3. No Regulatory Response Required

It is not clear how this section relates to the product sales prohibition (Section 69506.6) and end of life management (Section 69506.8) response options. As currently written, it appears that § 69506.8, and potentially § 69506.6, will act as “default” regulatory responses and will be automatically implemented unless a finding is made that no regulatory response is required under this section. This is due to the language in both sections reading “except as provided in section 69506.3.” For obvious reasons, we believe that automatic triggers for any of the regulatory responses, including product information, will lead to unnecessarily burdensome results. Rather, DTSC should be required to carefully weigh and consider all of the factors delineated in § 69506(c) before deciding to impose any of its regulatory response options.

Section 69506.4. Product information for Consumers

As written, it appears that this regulatory response will be automatically required unless no Chemical of Concern is present above the applicable threshold. This automatic trigger seems unnecessary and could lead to information saturation for consumers on a wide scale. This is especially true given the amount of information required by subsection (a)(1). This requirement also includes some information that the manufacturer may not even have available, such as (a)(1)(C), or that may be considered confidential business information, such as the importer information in (a)(1)(F).

It would also be very difficult to fit this much information on the product packaging, and retailers will not voluntarily provide a placard at the point of sale. As we have stated in prior comments, the physical labeling of products is an outdated and inefficient solution that makes little sense for many types of

products. Research continues to show that beyond immediate hazards, labeling of a product is an ineffective way to warn consumers of potential hazards. Furthermore, information/disclosure requirements should be done in the least restrictive manner possible. Manufacturers should have options to labeling by providing information channels to consumers through the use of websites, product manuals, or other options that make sense for their market and for the potential hazard.

Section 69506.5. Use Restrictions on Chemical(s) of Concern and Consumer Products

It is not clear how restrictions on the use of consumer products can be enforced. While information on use restrictions can certainly be made available, how would the Department ensure compliance with such restrictions?

Section 69506.6. Product Sales Prohibition

As stated above, it is not clear how the tie-in to Section 69506.3 would work in practice for the product sales prohibition response option. Additionally, how would the Department know which products contain any Chemical of Concern above the applicable alternative analysis threshold, and which do not? Again, there may not be tests available for determining the presence of a particular material in a product, making these determinations and enforcement challenging.

This section is also made unnecessarily burdensome by allowing the Department to still prohibit the sale of a product even if no viable alternatives exists (see subsection (d)(1)), and by requiring responsible entities to notify DTSC if their product does not contain a Chemical of Concern.

Section 69506.7. Engineered Safety Measures or Administrative Controls

We would suggest that this section use the term “accessibility” rather than “integrally contain” in subsection (b), as there are defined tests for accessibility, making it a more objective standard for compliance. Thus, page 57, subsection (b), line 16 would read: “limit accessibility to the Chemical(s) of Concern within the structure of the product or limit...”

Additionally, we believe that there needs to be thresholds for presence under subsection (b)(1) as Chemicals of Concern, metabolites, or others may be naturally occurring or have multiple metabolites. Simply requiring “presence” is too ambiguous of a standard to be useful here. Also, as written, presence in a single building would be sufficient to trigger administrative control under (b)(2), which we think is unnecessarily strict.

Section 69506.8. End-of-Life Management Requirements

As stated earlier, it appears that this regulatory response will be automatically imposed unless the Department finds that there is no need for any regulatory response under § 69506.3. Automatically requiring end-of-life management requirements would lead to unnecessarily burdensome results as comprehensive product stewardship plans are very significant undertakings – logistically, financially, and otherwise – that should not be imposed absent careful consideration of all factors delineated in § 69506(c).

In addition, a one year time frame given in subsection (a)(2) is far too short for entities to implement the complex take-back schemes envisioned by this section, and it is unclear what financial guarantees, if any, would be adequate or available to entities under (a)(2)(A)(7). An additional concern is that this section does not differentiate between Business to Business (B2B) markets and consumer markets; there are viable markets for B2B recycling in many instances and the regulation should not undermine the free markets here.

The report required under (a)(2)(D) is also problematic. First, information on state sales and recycling is likely not available – most sales are done through distributors and manufacturers have no way to track what is sold in state. Additionally, and especially in the electronics industry, there is a vibrant post-consumer market, which would also make tracking recovery very difficult. And for durable products especially, which have lifespans of several years, the amount of goods recovered in a given year will have no relation to the amount of goods sold, which could give the impression to the Department that a program is performing poorly when in fact it is not.

Finally, it is unclear how a manufacturer might be able to prove to DTSC that an end-of-life management program is not feasible under subsection (d), though we agree that responsible entities should have the opportunity to show why they should be exempt from the requirement.

Section 69506.9. Advancement of Green Chemistry and Green Engineering

This section states that DTSC may “require” a manufacturer to conduct research and development, or fund a challenge grant, to design, improve, reduce the cost of, or increase the market penetration of, a safer alternative to a Priority Product. Since any given manufacturer might not have the resources to undertake such project, or might believe that such projects are not likely to be successful, a manufacturer should always have the option of discontinuing manufacture of the Priority Product. Section 69506.9 should be amended to provide explicitly that a manufacturer can choose to discontinue manufacturing a Priority Product instead of complying with any requirement issued pursuant to this section.

Additionally, many companies are engaging in research and development to achieve the goals specified in subparts (a) – (d), independent of the mandates in this regulation. These companies should be given

credit for their independent efforts as it relates to this regulatory response, and any further mandated funding of R&D needs to come with IP protection for the responsible entity.

Section 69506.10. Regulatory Response Selection and Re-Evaluation

As written, it is not clear what other situations DTSC is referring to in subsection (a), or why this section is needed to begin with. This section seems to remove any of the constraints imposed by earlier sections by stating that DTSC “may impose one or more regulatory responses ... to situations other than those specified in those section.” If that is the case, what could the Department not impose as a result of this section? We would request clarification on this point.

Additionally, the term “periodically” needs to be further defined or clarified in subsection (b). It would be unnecessary and burdensome to review regulatory responses too frequently. Entities need certainty with the responses they are required to comply with in order to do business.

Section 69506.11. Exemption from Regulatory Response Requirements

As written, this section appears duplicative of work that the Department should have presumably already completed: the determination of conflicting or duplicative regulatory programs. If the product is already covered by California or other regulatory programs elsewhere, the product should already be exempt from these requirements. The responsible entity should not have to do an alternatives analysis and then put in a formal request to DTSC for exemption to demonstrate that a conflict exists with other regulatory schemes. That determination should have already been made.

We would suggest that a responsible entity be able to request and receive exemption for compliance with international law, such as RoHS or REACH, provided that the manufacturer can show compliance and that the international law will also provide health and environmental benefits.

Section 69506.12 Regulatory Response Report and Notifications

As written, we believe this section is very problematic and fundamentally ignores the realities of supply chains and commerce. Manufacturers rarely sell directly to a retailer and thus will not be able to identify the retailers required to comply with subsection (a). We would suggest rather that the manufacturer notify whoever it is they are directly selling the product to if it is reasonably likely that the product will be sold in California. Then, the entity selling or distributing the product would be obligated to notify the appropriate retailers.

We believe the regulatory response notice to the Department required under subsection (c) is unnecessary, as DTSC should assume but confirm compliance as needed, such as by requesting compliance documentation.

Article 7. Dispute Resolution Processes

Section 69507. Dispute Resolution

It is not clear why articles 2, 4 and 10 are not subject to dispute resolution. We would think that the DTSC would welcome the opportunity to informally arbitrate any decision made pursuant to the Regulation. We would think an information dispute process would help these articles; otherwise injunctive relief through the courts would be the only process open should a dispute arise. We suggest allowing all Articles to have some sort of administrative dispute process.

Section 69507.1. Informal Dispute Resolution Procedures

We submit that allowing only 30 days to dispute an action, especially notice on the Department's website, is inadequate. In many cases, it may take 30 days for a responsible entity to realize they are involved and decide to dispute a posting. We suggest at least 90 days for this initial time.

Article 8. Accreditation Bodies and Certified Assessors

ITI, TechAmerica, CEA, and SIA strongly assert that the Certified Assessor process as described in Article 8 will not serve to meet the goals of the Green Chemistry Initiative to ensure that 1) the alternative assessments are conducted by a person with all of the expertise necessary to adequately complete an assessment, and 2) that assessments will be done within the expected requirements for compliance with the law, thoroughness, and scientific rigor. For the reasons described in comments to previous sections and below, we urge the DTSC to remove Article 8.

Simply put, the Certified Assessor requirement will increase the costs to do the AAs, with absolutely no benefit. Most small companies will need to hire a third-party assessor, and larger companies will likely assume the expense of getting one or more of their technical experts certified. Most certified assessors will not have the specific product knowledge, especially if they are not experts in the industry they are trying to assess, to perform an assessment. Simply requiring a bachelor's degree in a scientific field and training on the requirements of these regulations will not ensure that the assessors will have the knowledge base to adequately perform an assessment. The assessor must have knowledge of the tools being used to perform the assessment (which will vary depending on the type of material and product assessed), knowledge of the industry being assessed, and the expertise to be able to weigh the factors and assess the information used to perform the assessment. No certification program will ever be able to provide this level of expertise.

As we have mentioned previously, the use of third-party certified assessors will likely create potential legal issues. For example, who will be liable for any material use decision based on the outcome of an

assessment? What happens if the manufacturer disagrees with the assessor? What if multiple assessors are used (either in different manufacturers of the same product, or even within a single assessment) and the assessors disagree on the optimal outcome? Who will resolve any conflicting findings?

Recommendation:

Delete Article 8. The Department reviews all submissions for compliance with the regulations in section 69505.6 and has provided for a process to audit any AAs submitted under Article 9. We believe this is adequate protection to ensure that the assessments are done correctly, and the Department has the ability to review the AAs in depth for compliance, information quality and adequacy of the analysis.

Article 10. Trade Secret Protection

Section 69510. Assertion of a Claim of Trade Secret Protection

The electronics industry believes that a reasonable protection of confidential business information (CBI) is critical to innovation and competition in the market. As mentioned earlier, the Proposed Regulation would require manufacturers to supply a substantial amount of information to the DTSC, including sales and manufacturing process information. The submittal of such a broad range of potentially sensitive information increases the likelihood and frequency that a manufacturer may have to rely upon the regulation's trade secret provisions in order to safeguard its CBI.

Under Section 69510(a), a claim for trade secret protection will involve the submittal of extensive supporting information to the DTSC in order to substantiate its need for trade secret protection. A disagreement from the DTSC in the trade secret claim would mean that the manufacturer would need to cure the perceived deficiencies in the trade secret claim or seek judicial review in order to prevent the CBI from being released to the public (Section 69510.1).

This resource-intensive CBI claim process strongly emphasizes the need for the Department to carefully consider what information it truly requires from regulated entities throughout the Regulation. Thus, we urge the Department to limit submission requirements only to that information which is absolutely necessary for DTSC to implement the Regulation. This will help reduce unnecessary compliance burdens and help ensure that CBI is properly protected.

Further, this section of the regulations should focus on the interrelationship of the new Safer Consumer Products law with existing California laws on trade secrets. California Civil Code § 3426.1 provides:

(d) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one would need to show that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by DTSC under California Health and Safety Code §25257(d) should logically begin by looking at those two questions. While it seems that the gist of each of these two questions is addressed in subpart (a) of the document, subpart (b) requires, by itself, the submission of a large quantity of information, on top of the already large quantity of information that is being requested by the Proposed Regulation. Further, if any of the Trade Secret claims themselves are claimed to be Trade Secret, the entire process of subparts (a) must be submitted as per subpart (b), setting up a potential feedback loop of data submissions to the department. In particular, subparts (a)(4-8) will almost invariably involve trade secret information.

The exclusion of all chemical identity information in subpart (f) is overly broad due to the broad definition of “hazard trait” found in OEHHA’s supporting regulations. For example, a chemical with the hazard trait of “irritation” cannot be claimed as a trade secret, even if it is not being assessed for that trait. Often, chemical identity is the most closely guarded trade secret, and, as drafted, the Proposed Regulation will substantially reduce the ability to protect such intellectual property.

For subpart (g), how does a manufacturer establish a chemical use is a “new use?” Proving that a chemical has never been used is difficult.

Section 69510.1. Department Review of Claims of Trade Secret Protection

As mentioned in our comments to section 69507, it is not clear why the DTSC would not subject these determinations to an agency review process. We appreciate that the DTSC has included in subpart (d) that the Department may not disclose information until a court proceeding is finished; however we are still concerned with the timelines, in particular subpart (b)(2). It is unlikely that a manufacturer will be able to respond or file an action in 30 days.

Conclusions

ITI, TechAmerica, CEA and SIA wish to thank the Department for its ongoing work on the Proposed Safer Consumer Product regulation, and feel that the proposed regulations contain several significant improvements compared to previous drafts. However, we are very concerned with the lack of specificity in several sections of the regulations, the immense data submission burdens, the required use of certified assessors, and the very weak trade secret protections offered in the draft regulations. We share the Department’s goals of a meaningful and workable regulation, but unfortunately feel that the proposed regulations contain several sections, as outlined above, that would make these difficult for industry to interpret and meet, as well as for the Department to enforce. We look forward to continuing to work with the DTSC to finalize a workable set of regulations in a manner that will focus on the chemicals and products that pose the greatest risk.

If you have any questions, please do not hesitate to contact Chris Cleet at (202) 626-5759 or cleet@itic.org, Robert Callahan at (916) 443-9088 or robert.callahan@techamerica.org, Allison Schumacher at (703) 907-7631 or aschumacher@ce.org, or David Isaacs at (202) 446-1709 or DIsaacs@sia-online.org.

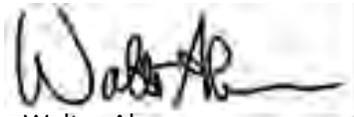
Sincerely,



Chris Cleet, QEP
Director, Environment and Sustainability
Information Technology Industry Council (ITI)
1101 K Street, NW Suite 610
Washington, DC 20005
202.626.5759
www.itic.org



Robert Callahan
Director, State Government Affairs
TechAmerica
1107 9th Street, Suite 850
Sacramento, CA 95814
916.443.9088
www.techamerica.org



Walter Alcorn
Vice President, Environmental Affairs and
Industry Sustainability
Consumer Electronics Association
1919 South Eads Street
Arlington, VA 22202
(703) 907-7765
www.ce.org



David Isaacs
Vice President, Government Affairs
Semiconductor Industry Association
1101 K Street, NW Suite 450
Washington, DC 2005
(202) 446-1709
www.sia-online.org

About ITI

The Information Technology Industry Council (ITI) is the premier advocacy and policy organization for the world's leading innovation companies. Founded in 1916, we have earned the trust of the world's most recognized technology brands to solve their most complex policy challenges. Learn more about ITI at www.itic.org

About TechAmerica

TechAmerica is the leading voice for the U.S. technology industry – the driving force behind productivity growth and jobs creation in the United States and the foundation of the global innovation economy. Representing approximately 1,000 member companies of all sizes from the public and commercial sectors of the economy, it is the industry's largest advocacy organization and is dedicated to helping members' top and bottom lines. TechAmerica is also the technology industry's only grassroots-to-global advocacy network, with offices in state capitals around the United States, Washington, D.C., Europe (Brussels) and Asia (Beijing). Learn more about TechAmerica at www.techamerica.org.

About CEA

The Consumer Electronics Association® ("CEA") represents more than 2,000 companies involved in the design, development, manufacturing, distribution and integration of audio, video, in-vehicle electronics, wireless and landline communications, information technology, home networking, multimedia and accessory products, as well as related services that are sold through consumer channels.

About SIA

The Semiconductor Industry Association (SIA) is the voice of the U.S. semiconductor industry, one of America's top export industries and a bellwether measurement of the U.S. economy. Semiconductor innovations form the foundation for America's \$1.1 trillion dollar technology industry affecting a U.S. workforce of nearly 6 million. Founded in 1977 by five microelectronics pioneers, SIA unites over 60 companies that account for 80 percent of the semiconductor production of this country. Through this coalition SIA seeks to strengthen U.S. leadership of semiconductor design and manufacturing by working with Congress, the Administration and other key groups. The SIA works to encourage policies and regulations that fuel innovation, propel business and drive international competition in order to maintain a thriving semiconductor industry in the United States. Learn more at www.sia-online.org.



European Semiconductor Industry Association

October 11th, 2012

Ms. Krysia Von Burg
Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
U.S.A.

Re: Comments of the European Semiconductor Industry Association on Proposed Safer Consumer Products Regulations, California Regulatory Notice Register (Z-2012-0717-04) published on July 27, 2012

Dear Ms. Von Burg:

On behalf of the European Semiconductor Industry Association we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxic Substances Control (DTSC), published in the California Regulatory Notice Register (file number Z-2012-0717-04) on July 27, 2012.

European Semiconductor Industry Association is the trade association of the European based semiconductor industry. More information about our organization can be found at <https://www.eeca.eu/esia>.

We are writing in support of the comments filed on October 11, 2012 by several technology associations based in the United States. The organizations are the Information Technology Industry Council (ITIC), TechAmerica, the Consumer Electronics Association (CEA), and the Semiconductor Industry Association (SIA) in the United States. The ESIA members have reviewed the comments of these other technology associations and we endorse these views. As discussed in detail in those comments, we believe that these proposed regulations set forth a burdensome and subjective regulatory scheme that will be unfeasible and expensive for manufactured products such as semiconductors. In addition, we believe that some requirements may represent a technical barrier to trade (TBT) under the rules of the World Trade Organization (WTO), and could result in the disclosure of trade secrets and confidential business information (CBI).

We appreciate the opportunity to provide input on these proposed regulations.

Yours sincerely,

Hendrik Abma
Director General ESIA

cc: Odette Madriago, Deputy Director(omadriago@dtsc.ca.gov)

Jeff Wong, Chief Scientist (jwong@dtsc.ca.gov)

ABOUT ESIA

ESIA represents and promotes the interests of the European-based semiconductor industry and advocates for its international competitiveness. The industry provides the key enabling technology solutions for society in the fields of energy efficiency, mobility, healthcare, security and across the ICT sector including the realisation of the smart grid and more efficient lighting. The industry was ranked as the most R&D intensive sector by the European Commission in 2011. This sector supports around 110.000 jobs directly and up to 500.000 jobs in Europe, operating in a worldwide market valued at over \$299 billion (over €215 billion) in 2011.

Our website provides further information on ESIA's activities: <https://www.eeca.eu/esia/>



EUROPEAN COMMISSION
 ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Regulatory policy
 Notification of technical regulations

Brussels,
 LK/nv – entr.c.3(2012)1225848

E-MAIL

To: TBT Enquiry Point of the United States **E-mail:** ncsci@nist.gov

Copy Ms M P Nicora
 EU Delegation of the United States

From: Mr Giuseppe Casella **Telephone:** + 32 2 295 63 96
 EU-WTO-TBT Enquiry Point **E-mail:** eu-tbt@ec.europa.eu

Number of pages: 1 + 12

Subject: **G/TBT/N/USA/727 – DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS" – EU comments**

Message:

Dear Sir or Madam

Please find attached the comments from the European Union on the above-mentioned notification.

Could you please acknowledge receipt of this e-mail? Thank you.

Yours faithfully

Giuseppe Casella
 Head of Unit

Contact: Mr László Kojnok
 Telephone: (32-2) 295 09 08.
 E-mail : eu-tbt@ec.europa.eu

**COMMENTS FROM THE EUROPEAN UNION CONCERNING
NOTIFICATION G/TBT/N/USA/727**

**DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL
(DTSC) ON "SAFER CONSUMER PRODUCTS"**

The European Union (EU) would hereby like to submit comments on the draft Regulation of the California Department of Toxic Substances Control (hereinafter "DTSC") on Safer Consumer Products, which was notified on 8 August 2012.

The EU would like to thank the US authorities for the notification of the draft Regulation, as this allows the EU and other trade partners of the US to comment on it. This draft establishes a number of direct obligations for producers of chemical substances, mixtures and articles, as soon as the substance, mixture or article is listed as a so called "Priority Product" and contains a so-called "Chemical of Concern". Whilst the draft Regulation does not yet list specific products or specific substances, all the conditions and requirements that companies eventually have to comply with are already contained in the draft Regulation and cannot be changed at a later stage.

The EU will first provide general observations on the principles of the draft Regulation and then offer more detailed comments on the text itself.

General Comments

First of all, the EU would like to underline that it fully shares the objectives of the draft Regulation, namely to achieve a high level of protection of human health and the environment by substituting the most hazardous chemicals with safer alternatives and adequately informing users about the risks from chemicals. To this effect, the EU has put into place, among others, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as "REACH" and "CLP" Regulations).

The EU would, therefore, also like to share with the Californian authorities some of the experience gained with regard to the adoption and application of the above-mentioned Regulations.

With regard to the main principles of the draft Regulation, the EU is concerned about three issues, which will be explained in more detail below:

- potential for unequal treatment of economic operators,
- extreme complexity of the proposed alternative assessment procedure and high administrative burdens related to its implementation raising concerns about their compatibility with Article 5.1.2 of the TBT Agreement and

- creation of a highly specific accreditation and certification system which seems to be disproportionate in view of Article 5.1.2 of the TBT Agreement and moreover could potentially disadvantage manufacturers located in third countries (Article 5.1.1 of the TBT Agreement).
- 1. Several provisions of the draft Regulation have the potential of discriminatory effects among the so-called "responsible entities" (i.e. manufacturers, importers or retailers), both at the beginning and the end of the process.

For example, under § 69501.4 (a) (3) and (4) of the draft Regulation, DTSC can request a responsible entity or a chemical manufacturer or importer to make existing information available to DTSC within a specified time frame, or even oblige an economic operator to generate new information and provide it to DTSC. Failure to do so results in the responsible entity being "black-listed" on the 'Response Status List' of DTSC in accordance with § 69501.4 (c). However, a responsible entity not known to DTSC or not having been asked to provide information will not appear on this list, without the stigma of having failed to respond to requests from DTSC. Hence, solely the fact of being known or not known to DTSC will potentially lead to discriminatory consequences for responsible entities.

According to §69503.7 responsible entities must submit priority product notifications, following the listing of the priority products concerned by DTSC. However, if companies do not identify their products themselves, they will not be known to DTSC and will be spared the burdensome consequences of conducting an alternative analysis and of implementing regulatory response(s). The EU would like to ask how DTSC will ensure that all duty holders will be treated equally given that at the time of listing priority products, DTSC will not have a complete market overview.

According to § 69505.1 (f), a responsible entity may fulfil its requirements to conduct an alternative analysis (hereinafter "AA") by submitting to DTSC a report for a previously completed AA for the priority product. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection). Consequently, the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

After having conducted the alternative analysis, different responsible entities marketing the same (or very similar) priority product(s) with the same chemicals of concern, can come to very different results – some being able to replace the priority product or chemical of concern, while others might not and hence propose different 'regulatory responses'. Whilst DTSC will review the proposed regulatory responses, it is not clear from the draft Regulation that DTSC will actually require in such circumstances that all entities have to replace the product or chemical of concern, or whether DTSC will indeed impose one or several regulatory response(s), which could again be different for the responsible entities.

Lastly, some of the regulatory responses that DTSC can impose also have the potential of having very different consequences for responsible entities, in particular when these are small or medium-sized enterprises (SME) or located

outside California. For example, an SME (or an importer on behalf of an SME manufacturer outside California) selling only relatively few priority products will never be able to set up the very demanding and costly End-of-Life Management Requirements described under § 69506.8; whilst this might well be feasible for a big company imposing this regulatory response it would, *de facto*, amount to a ban for the SME producer. Likewise, DTSC can impose the regulatory response to fund research and development projects for the advancement of Green Chemistry and Green Engineering (§ 69506.9), but there is no indication as to which amount(s) will be involved. In order to avoid disadvantages for SMEs, there should preferably be a link with a certain percentage of the turnover made with the priority product in question.

2. The EU would like to elaborate below on the provisions of the draft Regulation related to the alternative assessment procedure and the administrative burdens related to the implementation, with respect to which it has concerns about their compatibility with Article 5.1.2 of the TBT Agreement.

First of all, the EU would like to note that the US Government is taking strong efforts in recent years to reduce and avoid administrative burdens for businesses. Accordingly, the Californian proposal seems to be at odds with the US 'smart regulation' policies and principles. In particular, the EU would like to refer to Executive Order 13563 of January 18, 2011 on Improving Regulation and Regulatory Review, which notably provides that the US regulatory system must: promote predictability and reduce uncertainty; identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends; take into account benefits and costs, both quantitative and qualitative; ensure that regulations are accessible, consistent, written in plain language, and easy to understand and measure, and seek to improve, the actual results of regulatory requirements.

The alternative analysis (AA) as described in Article 5 is excessively complex as the range of factors to be analysed is extremely broad and will require huge amounts of data that might be very difficult to obtain. In particular, responsible entities that are SMEs might well not be able to find all relevant data, not even with the help of a certified assessor – or, if so, only at very high cost compared to the company's financial means. It is regrettable that in its analysis of economic impacts DTSC has not actually analysed a few case studies (e.g. a simple case of a chemical mixture and a more complex case of an article composed of many components) to actually demonstrate that the prescribed AA is feasible within the given amount of time and at what costs¹ (even leaving aside the actual costs for substituting the chemical of concern). This type of analysis for processes and procedures was conducted by the EU before REACH was adopted - in fact, this had been strongly called for by economic operators and third countries, including the US, and this has ultimately helped to modify a number of provisions in

¹ In fact, in the attachment to the Economic and Fiscal Impact Statement, DTSC merely states on pages 4 and 5 that costs could vary between a few thousand dollars and hundreds of thousands of dollars, which is not very informative. Analysis of a few real case studies as for example conducted in the electronics industry and/or the US EPA Design for the Environment Programme would probably have provided more concrete estimates, both for costs and the necessary time.

REACH in comparison to how they were originally envisaged². The EU would therefore call on DTSC to reflect on ways that the AA can be simplified, for example in the guidance that is to be developed in accordance with § 69505, or by designating a more limited and specific range of parameters to be analysed when listing a priority product and chemical(s) of concern according to § 69503.4.

The numerous (and in themselves already rather complex) notifications and reports to be submitted by the responsible entities to DTSC, their evaluation by DTSC (within rather short periods of time), the various notices of approval or deficiencies, further submissions and updates of already submitted AA reports, as well as possibilities for administrative disputes etc. could often be duplicative and bear the risk that DTSC might quickly become overwhelmed by the programme. For example, if, as projected, the first list of priority products contains 5 products and each of these is marketed in California by 10 responsible entities, DTSC would have to deal with 50 product notifications (a certain % of which might require follow-up), up to 50 preliminary AA reports (again a certain % of which might require follow-up actions), and up to 50 final AA reports, each probably containing several hundred pages and complex information, many being different from each other in terms of content and quality, all to be analysed by DTSC within 60 days and, if necessary followed-up with complementary submissions by the responsible entities concerned. In parallel, DTSC will have to continue the (also rather demanding) work of identifying further priority products and chemicals of concern and many other activities.

The EU would like to ask whether DTSC has considered an alternative way of crafting the process, which would avoid duplicative work for both responsible entities and DTSC and correspond more to the Restrictions Title under REACH or the Canadian Chemicals Management Plan. For example, after designating a priority product and its chemical(s) of concern and thus requiring responsible entities to notify the priority products, DTSC could then call for submission of all relevant data by a certain date from these responsible entities and all other stakeholders (including the NGO Community) and itself conduct the alternative analysis (either in house, with the help of the Green Ribbon Science Panel, or an outside assessor – in the latter case, costs could be split among all responsible entities having been identified with the priority product notification process according to their turnover with the priority product), and then determine directly a regulatory response. This could well be more efficient in terms of resources required and the necessary time for implementation and would ensure equal treatment of all responsible entities. In fact, in order to be able to review AA prepared by responsible entities and decide on their being appropriate (as required by section § 69505.6) DTSC will in any case need the expertise required for conducting AA and by having to conduct and review multiple AA for the same (or similar) priority product(s) with potentially different outcomes for each of them, the overall workload is multiplied compared to one single analysis. Such an alternative has, unfortunately, not been evaluated under section D of the Economic and Fiscal Impact Statement, where the alternatives considered are all based on the concept that the AA has to be conducted by responsible entities, while nothing in Assembly Bill 1879 on which this draft Regulation is based actually so requires.

² Further information is available at:
http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

3. Furthermore, the EU would like to elaborate below on the provisions of the draft Regulation related to the accreditation and certification system, with respect to which it has concerns about their compatibility with Article 5.1.1 and Article 5.1.2 of the TBT Agreement.

Article 8 of the draft Regulation establishes a very specific and highly challenging system for the recognition of accreditation bodies who in turn can certify assessors according to very demanding criteria. This creates a serious risk of disadvantaging potential accreditation bodies and potential assessors not located in California. The required qualifications for accreditation bodies cover such a broad range of topics, while also being highly specific, that probably only a university can fulfil them (e.g. extensive experience in teaching and the need to present entire curricula when applying for accreditation combined with knowledge of Federal and State regulatory and statutory requirements for various areas etc.). In addition, the requirements for assessors to become (and remain) certified are very strict and the time frame for DTSC to designate accreditation bodies and for assessors to pass the necessary training and certification process is short. The EU would be interested to know on which basis DTSC has determined that there will be enough certified assessors to conduct all AA as of 2016 – the study underpinning the Economic and Fiscal Impact Statement mentions on page 15 that there could well be a shortage of certified assessors leading to high fees for responsible entities and then claims – albeit without much evidence – that in the long run, firms and individuals seeking profits will attain the accreditation necessary to perform alternative analysis. However, there is no information related to the costs that an interested assessor may face in order to obtain certification, which depending on the amount involved could be a strong deterrent to seek certification.

In this context, the EU would also like to recall that the delegation of the United States to the WTO circulated on 12 March 2012 a Communication on the use of the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA) by Central Government Bodies, which stated that on 12 January 2012, three White House agencies – the Office of Information and Regulatory Affairs, the Office of Science and Technology Policy and the Office of the U.S. Trade Representative – issued a memorandum for the heads of Executive Departments and Agencies entitled "*Principles for Federal Engagement in Standards Activities to Address National Priorities*", which, among other things contained guidance aimed to strengthen implementation of Article 9 of the TBT Agreement:

"Agencies should evaluate whether their objectives necessitate creating government-unique conformity assessment schemes, which may be expensive to develop and maintain, may impose additional costs on the private sector, and may not be recognized beyond national boundaries. In doing so, agencies should use existing best practices and leverage available resources in the private sector as well as within the Federal Government³."

³ <http://www.whitehouse.gov/sites/default/files/omb/memoranda/2012/m-12-08.pdf>

Article 8 of the draft Regulation seems to run counter to this US Policy, by setting up a highly unique accreditation and certification scheme that is not recognised beyond State boundaries.

Specific comments:

In the following, the EU will comment on the various sections of the draft Regulation in their order of appearance in the draft text.

Article 1:

§ 69501.1. Definitions

Page 6, lines 10-16: It seems highly unlikely that a chemical substance could have the adverse impacts mentioned under points (A) or (B), and (D) could only materialise if the chemical was intentionally used for that purpose (e.g. asphalt or concrete).

Page 8, lines 10 to 17: The definition of "chemical" is rather specific and not in line with international standards such as "substance" and 'mixture' defined in the UN Globally Harmonised System (GHS). This can lead to confusion and clarity could be increased by specifying that a chemical is either a substance or a mixture and then using the definitions of the UN GHS for these two terms.

Page 8, lines 18 to 21: The definition for the term "molecular identity" is somewhat confusing and includes parameters that go well beyond molecular characteristics. It might be better to use the term 'substance identity'.

Page 10, lines 11 to 14: It is unclear why the term "import" also includes imports into the rest of the United States. It might well be that manufacturers in third countries do not import into California and the Regulation would, therefore, not be applicable to them (or their importers). It should be clarified that the Regulation only applies to products actually placed on the market in California.

Page 13, lines 9 to 10: The final part of the definition of a "retailer" is somewhat confusing. According to the Health and Safety Code in California, the term 'Consumer Product' includes also products sold to professional users. A retailer selling such a product to professionals would, therefore, also be covered by the rules of the Regulation, whilst this definition seems to suggest that this is not actually the case.

§ 69501.3. Information Submission and Retention Requirements

Page 17, lines 5 to 6: When and where will the "manner and electronic format" for data submission be specified? Will DTSC consider using internationally recognised formats such as International Uniform Chemical Information Database (IUCLID)?

§ 69501.4. Chemical and Product Information

As already commented above, the provisions of this paragraph lead to potentially discriminatory treatment between responsible entities solely due to whether they are known to DTSC and receive requests for input or not. An arbitrary selection of

economic operators for soliciting information would create obligations for some but not for others. The EU would like to seek clarification on whether this provision includes also manufacturers in third countries and how DTSC will ensure that they have the same possibilities to act as manufacturers in the US, given that they might not be aware of the obligations under the Regulation and correspondence/communication might not be as easy as with manufacturers based in California (or in the US). In addition, the public listing of companies for having failed to respond to requests from DTSC for information even before a decision has been taken on whether or not a product and/or chemical of concern will be selected for prioritisation is not justified. Rather than contacting individual companies with information requests and denouncing companies for not having submitted information at this stage of the process, DTSC might wish to limit the information requests to general calls as specified in subsection (b)(2) and then publish the names of those companies that have co-operated and responded. This would then be a reward and incentive for companies to participate in line with what is already foreseen in section (d).

Page 18, lines 34 to 35: How will the quality and integrity of voluntary AA be evaluated? Whilst a detailed process is laid out in § 6505.2 to 5 for responsible entities to conduct a "mandatory" AA and in §69505.6 for DTSC to verify the results of a "mandatory" AA, there seems to be no such verification for voluntary AA.

§ 69501.5. Availability of Information on the Department's Website

This paragraph sets out a long list of information to be made available on DTSC's website, much of which will require almost constant updating. As this will be very resource-intensive and bears a high risk of displaying inaccurate information, DTSC might wish to consider prioritisation of a more selected list of information for publication. Has DTSC ensured that the publication of the names of individual persons (e.g. as required by subsection (b)(3)(D) the person that will fulfil the requirements of article 5) is compatible with rules on the protection of personal data?

§ 69502.2. Chemicals of Concern Identification

Page 21, lines 30 to 32. The EU supports that the draft Regulation refers to substances classified in the EU and also to other recognised classifications. As an editorial remark, the EU would suggest that the correct wording of the reference in point (B) should rather be as follows:

"(B) Chemicals classified as carcinogens, mutagens and/or reproductive toxicants Categories 1A or 1B in Annex VI to Regulation (EC) No 1272/2008"

The EU notes that the legal certainty for references to lists of endocrine disruptors and persistent, bioaccumulative and toxic substances as indicated in points (C) and (G) could be improved by reference to those that have been officially identified for these characteristics in accordance with the procedure outlined in Article 59 of REACH:

"(C) Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH as endocrine disruptors⁴.

.....

⁴ The list is available at: <http://echa.europa.eu/candidate-list-table>

(G) *Substances that have been included in the candidate list of substances of very high concern in accordance with Article 59 of REACH for being persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative."*

§ 69503.4. Priority Products List

Page 29, line 35: Why has a criterion of more than 100 manufactured components been selected to identify a 'highly durable product'? There can be many highly durable goods with less than 100 components, for example furniture, mattresses, carpets etc.

Page 30, lines 3 to 4: A reference to products that are '*dispersed as an aerosol or vapour, or applied to hard surfaces with the likelihood of runoff or volatilization*' in the context of highly durable goods seems misplaced. By their very nature, these products cannot be highly durable goods.

Page 30, lines 35 to 38: How will priority products be identified in the list? By (more) general descriptors of purpose and function, or by individual brand names? It could be very important for companies to know this in order to assess whether their products are concerned or not. Also, can DTSC provide an estimate of how many chemicals of concern will be identified in the initial list as the reason for listing the (up to five) priority products?

§ 69503.7. Priority Product Notifications

The EU would be interested to learn how DTSC will ensure that all responsible entities concerned will comply with their obligations under this paragraph, which is also the basis for all subsequent obligations. Point (b) sets out the consequences of a failure to comply, but does not describe any steps that DTSC will take in order to determine cases of non-compliance. This is not set out in the draft Regulation, nor in the Initial Statement of Reasons.

Article 5. Alternatives Analysis

As already pointed out above, the requirements in the draft Regulation for conducting alternatives analysis (AA) are highly complex, both technically/content-wise and administratively with multiple notifications and submissions of reports, each of which will require reactions by DTSC and the submitting entities. The time periods foreseen for completing the various steps seem short compared to the tasks to be accomplished, in particular for preparing a final AA report (12 months) and for DTSC to review and react to the final report (60 days). For reasons of comparison, the EU would like to inform the US authorities that under REACH the normal time frame for preparing a request for authorisation for continued use of a substance on Annex XIV of REACH (which includes an analysis to demonstrate that there is no suitable alternative for the substance concerned) is between 18 and 24 months (while the range of parameters to be analysed is substantially narrower than in the draft Regulation of California), whilst the European Chemicals Agency (ECHA) has then one year to provide the opinions of its Risk Assessment Committee and its Socio-Economic Analysis Committee, before the Commission takes a formal decision on whether or not an authorisation for continued use of a substance can be granted.

Page 36, lines 4-7: The EU observes that it will be absolutely indispensable that California develops guidance for the implementation of the very demanding obligations that companies have to comply with under the draft Regulation. In particular for small and medium size companies it will be extremely difficult to conduct the required alternative analyses – even with guidance. Third country authorities and trade associations should be involved in the process for the development of such guidance documents. The EU also offers to make available the very extensive guidance that has been developed for the purposes of REACH and CLP, which could be a good starting point for the authorities in California.

Page 37, line 39-40: This provision specifies that *'Failure of the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request'*. However, what does this mean for a responsible entity having submitted a request without response within 30 days? It would need to know according to which timeline it has to prepare the AA.

Page 37, line 42 to Page 38, line 1: The draft Regulation requires that all AA completed on and after the date that is two years after the date on which the Regulation takes effect have to be conducted by assessors certified for the appropriate product type and industry sector. However, against the background of the very demanding process for obtaining certification (see comments above on Article 8), what evidence does DTSC have that there will be enough certified assessors available by that date and that their services can be procured at reasonable costs?

Page 38, lines 6 to 10: As already commented above, the provision to allow a responsible entity to fulfil its requirements to conduct an alternative analysis (AA) by submitting to DTSC a report for a previously completed AA for the Priority Product is problematic. There is no requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection) as otherwise the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

Page 39, lines 4-5: it seems excessive to require that responsible entities must summarise in their AA reports how they have made use of information made available on DTSC's website.

Page 34, lines 6-10: as already commented before, and for reasons of legal certainty, the Regulation should specify the consequences of DTSC's failure to react within the required deadline rather than specifying what this failure does not mean.

Page 40, lines 25 to 32: The provisions in this subsection are somewhat confusing as they seem to allow the placing on the market in California of new priority product(s) containing chemical(s) of concern (subject to the conduct of an AA within a certain deadline), even after the products have been listed, all responsible entities having already conducted their AA and DTSC having already imposed a regulatory response (which might actually be a ban or an obligation to replace a chemical of concern). This provision should, therefore, be limited until such time that DTSC has imposed a regulatory response for a given priority product after which any entity wishing to

market a new product would have to comply with the regulatory response. It seems not efficient to require another AA to be conducted then.

Page 42, line 31 to page 45, line 15: The EU would comment that the range of factors to be analysed during the second step of the AA is extremely broad, which makes it very difficult to conduct the analyses within reasonable cost and time. For many parameters it will be virtually impossible to find (or just model) the required data, and this will be even more complicated if products are manufactured in third countries. The EU notes that in the framework of the Economic and Fiscal Impact Statement DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate. The EU would also like to recall that in the development of the REACH Regulation, the Commission, the Member States and industry conducted numerous feasibility experiments – the so called Strategic Partnership on Reach Testing (SPORT) and Piloting REACH for Downstream Use and Communication in Europe (PRODUCE)⁵, the results of which led to significant changes between initial drafts and the final Regulation in the light of feasibility and proportionality considerations.

Page 46, lines 32 to 34: There is no particular reason to require this information as part of the AA as it does not bring any meaningful contribution to the analysis. In fact, the chemical industry and the broader manufacturing industries are operating globally. Even if a particular chemical is produced very close to a plant consuming this chemical in the manufacturing process of a product, that chemical (or an alternative) can easily be sourced from another country. It is also not clear what consequences this requirement would have for products manufactured in third countries.

Page 48, lines 10 to 11: It is unclear how a responsible entity could comply with this obligation. If certain information is not available, it is difficult to assess whether it would meet the criteria listed under points (A) to (C).

Page 48, line 34 to Page 49, line 22: This subsection establishes the obligation to determine the entire chemical composition of a selected alternative product. It will be extremely difficult in the case of complex products such as cars or household appliances to conduct an assessment of the entire chemical composition of each component in their product, as these are often assembled out of hundreds of different components, each containing potentially many different chemicals and provided by a variety of suppliers possibly in different countries. If DTSC maintains this requirement, it actually creates a strong incentive for responsible entities not to select an alternative and maintain the priority product as then they do not seem to have to comply with this obligation. A more feasible approach would be to limit the information requirement to whether the selected alternative contains other chemicals of concern.

Page 51, lines 1 to 10: as already commented before, the time frame for DTSC to review an AA report (60 days) and also the time frame for responsible entities to redress deficiencies (60 days) seem excessively short against the background of the complexity of the work required.

⁵ Further information is available at:

http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm

Article 6. Regulatory Responses

As a general question, what will DTSC do in the case of diverging or conflicting results of alternative assessment for the same/similar products and chemical(s) of concern? Given that many different actors will conduct AAs the risk that there will be diverging results with regard to regulatory responses will be quite high. Does § 69506.1 have to be understood in the sense that DTSC will ultimately impose the same regulatory response on all responsible entities or will there be different ones for different entities?

Page 53, lines 29 to 39: § 69506.2 entails again a significant risk of discriminatory treatment between responsible entities. If requests for additional information are made, they should concern all entities and not only individual ones. If one of them has already provided the information, DTSC could increase efficiency by using it and require all others to participate in the costs of the first one for generating the information, rather than requiring them to produce the same information again.

Page 54, lines 23 to 24: Is the intention really to require the listing of all chemicals of concern or rather the chemicals of concern due to which the product had been identified as a priority product? In fact, lines 34 – 35 specifically refer to the applicable alternatives analysis thresholds, which only exist for the chemicals of concern due to which the priority product had been selected.

Page 55, line 29 to page 57, line 5: It is not clear why DTSC wishes to operate with individual notifications to responsible entities to establish product sales prohibitions. Would it not be more efficient and less discriminatory, if, instead, DTSC established a horizontal rule prohibiting the product (or chemical of concern) in general and for all entities wishing to place it on the market in California?

Page 57, line 29 to page 59, line 17: The regulatory response to set up a comprehensive end-of-life management programme (including comprehensive financial guarantees and burdensome yearly reporting) seems impossible to meet for individual companies – in particular for manufacturers that are SMEs and/or located in third countries - and can probably only be achieved if the DTSC establishes a rule applicable to (a range of) products that would apply to all responsible entities to create this jointly. Again, the EU would like to know whether the DTSC has undertaken any feasibility studies with regard to this particular regulatory response, in particular for SMEs. In the light of the high costs involved, this regulatory response could amount to a disguised ban on marketing the product in California.

Page 59, lines 22 to 59: The EU would like to know according to which criteria the obligation to fund 'Green Chemistry' Research will be put into practice. How will the amounts be determined that a responsible entity will have to provide? As a share/percentage of overall sales? How will the DTSC avoid discriminatory treatment of different responsible entities?

Page 61, lines 18 to 24: Again, this subsection implies that different responsible entities will get different regulatory responses imposed for the same (or similar) priority product(s). It would seem more logical that DTSC informs all retailers and publishes general rules about one identical regulatory response applicable to all responsible entities in a non-discriminatory way.

Page 61, line 37 to page 62, line 22: these subsections establish burdensome reporting requirements for responsible entities and even more so for DTSC itself, as the number of products and regulatory responses concerned could easily run into the hundreds after a few years and would grow continuously over time.

Article 8: Accreditation Bodies and Certified Assessors

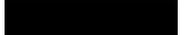
See comment number 3 in the section on general comments above.

The EU thanks the US authorities in advance for taking into account the above comments and looks forward receiving a reply.

GCREgs@DTSC

From: Patricia Everall <arev2@pacbell.net>
Sent: Monday, October 01, 2012 1:07 PM
To: GCREgs@DTSC
Subject: State Chemical Disclosure

A Sept. 16, New York Times Book review of Florence Williams' Breasts disclosed that the following chemicals are commonly found in women's breast milk: paint thinners, dry-cleaning fluids, wood preservatives, toilet deodorizers, cosmetic additives, gasoline by-products, rocket fuel, termite poisons, fungicides and varieties of flame retardants including Penta-BDE (banned in the EU). **Can there be any doubt that the regulations concerning chemical disclosure and removal need to be tightened???**

Patricia Everall


1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

October 11, 2012

Writer's Direct Access
Devon Wm. Hill
(202) 434-4279
hill@khlaw.com

Via Electronic and Regular Mail

Ms. Krysia Von Burg
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806
gcregs@dtsc.ca.gov

**Re: Comments on the Safer Consumer Product Alternatives
Proposed Regulation, Dept. Ref. No. R-2011-02, Office of
Administrative Law Notice File No. Z-2012-7017**

Dear Ms. Von Burg:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the *Safer Consumer Product Alternatives* (SCPA) proposed regulations published on July 27, 2012. The proposed regulations are intended to implement Article 14 of chapter 6.5, division 20, of the Health and Safety (H&S) Code (hereinafter, "the Green Chemistry Initiative" or GCI). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that collectively represent the majority of food contact materials suppliers in the United States, as well as trade associations that represent the food industry. This group has a critical interest in the availability of safe and effective materials for packaging, holding, storing, and transporting food products.¹

We respectfully submit that DTSC should exclude food contact materials from the SCPA because these materials are already subject to a comprehensive federal regulatory scheme that ensures their safety for the public health and the environment. The GCI prohibits DTSC from adopting regulations that duplicate or conflict with existing or pending regulations of other Agencies that are consistent with the purposes of the GCI. The Federal Food, Drug, and Cosmetic Act (FFDCA) and the Food and Drug Administration (FDA) fully regulates food

¹ Specifically, these comments are being submitted on behalf of the Grocery Manufacturers Association, the Society of the Plastics Industry, Inc., the American Forest and Paper Association, the Can Manufacturers Institute, the North American Metal Packaging Alliance, Inc., the Foodservice Packaging Institute, the Paperboard Packaging Council, and the Recycled Paperboard Technical Association.

contact materials through a comprehensive, science-based regulatory framework, rendering DTSC's further regulation of these materials under the GCI redundant and unnecessary. This additional layer of state regulation will, at the least, only duplicate the extensive and costly federal reviews already undertaken for these materials, resulting in higher costs for manufacturers as well as the inhibition of the technological innovation that develops safer and more environmentally friendly food packaging materials. More likely, the application of the SCPA to food contact materials will result in product deselection that could even force safe products out of the California market. For these reasons, DTSC should exempt food contact materials from the SCPA.

I. Introduction

Food packaging is an essential component in ensuring the safety and quality of food. Food contact materials are carefully designed to prevent the transfer of their components to food and to ensure that they do not affect the purity of the contacted food. These materials are selected to have technical properties that preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products. They are subject to a comprehensive, science-based federal regulatory program that protects the public health and environment from any adverse impacts that could potentially occur from their use in food packaging. Moreover, this program provides FDA the legal tools and authority to evaluate food contact materials prior to their arrival on the market, as well as the ability to remove these products from the market should a safety concern arise.

Food packaging materials are evaluated using a rigorous risk assessment approach, by scientists with extensive knowledge and training in complex scientific areas such as chemistry and toxicology, based on extensive scientific data. Yet the flexibility of the regulatory framework permits manufacturers to develop new, safer, and more environmentally friendly materials in response to market demand. The inclusion of food contact materials within California's SCPA regulation would subject these products to duplicative and potentially conflicting regulatory programs, without providing consumers any added safety benefit, and when the existing federal regulatory framework already addresses the purposes of the GCI. Moreover, DTSC's regulation would undermine the goals of the FFDCA, and potentially be directly contrary to FDA requirements. Therefore, DTSC should revise the SCPA to exclude food contact materials from the scope of the regulation, avoid regulatory duplication and focus limited public resources on the regulation of products that are not currently subject to thorough regulation and safety evaluations.

II. The Existing Federal Regulations of Food Contact Materials are Consistent With the Purposes of the GCI

The purpose of the Green Chemistry Initiative is to develop a comprehensive approach to chemicals policy, with the goal of creating a systematic, science-based process to evaluate

Chemicals of Concern, and identify safer alternatives to ensure product safety.² The GCI seeks to address what DTSC calls “structural weaknesses” in the federal Toxic Substances Control Act (TSCA),³ by compelling manufacturers to provide DTSC, and by extension, the public, information about the health and environmental effects of many chemicals used in consumer products. It certainly is the goal of our members to provide food contact materials (FCMs) that are safe, and FDA’s existing regulations ensure that this goal is met. The FFDCa establishes a legal framework prohibiting the use of unsafe materials in contact with food, and FDA implements this legal mandate through its review process. This framework grants FDA the authority to conduct premarket evaluations, as well as to remove unsafe products from the market. The flexibility of this framework also permits manufacturers to continue the research and development efforts that result in ever-safer and innovative food packaging material. Thus, FDA’s framework fully regulates the safety of every alternative substance used in contact with food and achieves the purposes of the GCI.

A. FCMs Are Regulated Through a Systematic, Science-Based Framework

Food contact materials already are the subject of a systemic, science-based review process that evaluates the chemicals used in the manufacture of these products, assesses the potential exposures, and ensures that any exposures are safe for the public health and environment. Indeed, FDA has assigned an entire office, the Division of Food Contact Notifications, which employs over 30 chemists, toxicologists, and other scientific staff, for the sole purpose of evaluating the safety and environmental impact of chemicals in FCMs. The collective decades of experience of the personnel in the Division all work to ensure that the packaging materials contacting food meet FDA’s safety standards.

DTSC’s Initial Statement of Reasons (ISOR) describes the structural weaknesses of TSCA that lead to the development of the GCI, particularly the fact that the burden of information collection under TSCA is placed on the Environmental Protection Agency (EPA) rather than on the chemical manufacturer, which has resulted in an alleged absence of data and information on the substances being regulated. Further, in the 45-Day Public Notice announcing the publication of the SCPA, DTSC reviews one of the reports that helped the development of the policy underlying the GCI: *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation*.⁴ This report identified three information gaps in federal

² See Initial Statement of Reasons (ISOR), page 8.

³ Title 15, U.S.C. § 2601 *et seq.*

⁴ Wilson M.P., Chia D.A., Ehlers B.C., “Green chemistry in California: a framework for leadership in chemicals policy and innovation,” 2006, available at <http://coeh.berkeley.edu/FINALgreenchemistryrpt.pdf>.

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 4

chemical policy: (1) a data gap, based on a lack of information on which chemicals are safe and what products they are in; (2) a safety gap, based on the rationale that government agencies do not have the legal tools or information to prioritize chemical hazards; and (3) a technology gap, which supposedly results in a lack of emphasis in industry on green chemistry principles. The report then connected those gaps to health and environmental damage occurring in California. Without addressing the merit of these conclusions, the simple fact is that these weaknesses and information gaps do not apply to FCMs.

As noted above, FCMs are regulated pursuant to the FFDCFA, which establishes a thorough legal framework for the safety of substances used in contact with food. The mandate of the FFDCFA is to ensure that the use of FCMs is safe throughout the country because most packaged food products are marketed nationwide, and many globally. Manufacturers must ensure the safety of their products for the public health and environment *before* placing the product in the marketplace. This premarket evaluation must be undertaken in accordance with extensive FDA regulations and guidance on how to determine whether a product is safe. Moreover, this premarket evaluation ensures that the gaps—data, safety, and technology—identified in the *Green Chemistry* report are not applicable to FCMs.

The rigorous premarket evaluation ensures that substantial amounts of data are available on FCMs and their potential exposures to the public and the environment. Any potential exposures must be evaluated to ensure there is no safety concern. The vast majority of materials used in the manufacture of FCMs are the subject of regulatory approvals in FDA's Indirect Food Additive Regulations or through other FDA programs,⁵ while the remainder are rigorously evaluated to ensure that there is no reasonable possibility of them becoming part of the food at unsafe levels. FDA is fully aware of the potential uses for FCMs and, if the Agency became aware that a particular use of a chemical was unsafe, could take regulatory action to remove the substance from the market.

Finally, the technology gap does not exist for FCMs because industry is highly active in producing materials that are "green." The recycling of FCMs has long been of interest for materials such as paper and plastic; indeed, FDA reviews recycling processes to ensure that any substances that may be present in the source material of a recycling stream do not contaminate the finished product or make it unsafe for use. New products are in development that are

⁵ FDA regulates FCMs through several programs in addition to the Indirect Additive Regulations. For example, FDA evaluates new food contact materials through its Food Contact Notification (FCN) program (see 21 C.F.R. § 170.100 *et seq.*). FDA can also determine that a substance is exempt from the need for premarket approval because the potential exposure from its intended use is so low that it cannot adversely impact the public health or environment, pursuant to a request for a Threshold of Regulation exemption (see 21. C.F.R. § 170.39).

biodegradable, compostable, or are manufactured using renewable and sustainable raw materials. Of course, the fast development of these products is tempered by the need to ensure that these new materials are safe for their use, a need met by the existing regulatory framework.

Among consumer products covered by the GCI, food packaging is unique. Other consumer products are inherently designed to contact the consumer or the environment, resulting in direct exposures that are substantially higher exposures than to any food contact substance. By contrast, substances used in food contact materials are often trapped within a matrix (*e.g.*, a polymer, coating or paper) that prevents their migration and limits exposure to very low levels. In fact, modern packaging is designed to be inert and to not transfer its components or have an effect on food. This designed safety complements FDA's thorough regulation of these materials. Thus, including FCMs within the SCPA would subject food contact materials to duplicative schemes, when FDA's regulation already is consistent with the purposes of the GCI.

B. The Existing Regulatory Framework Ensures the Safety of FCMs for the Public Health and the Environment

As noted above, the Food and Drug Administration, using the legislative authority granted by the Federal Food, Drug, and Cosmetic Act, has established a comprehensive regulatory scheme to ensure the safety of food contact materials from both a public health and environmental perspective. This regulatory scheme is wholly consistent with the goals and purposes of the GCI, and duplication of this regulatory scheme by the SCPA is prohibited by the GCI and is unnecessary. Specifically, the FFDCA establishes a premarket approval requirement for components of food packaging materials that may become significant components of food. In addition to the health and safety concerns with the use of the product, FDA also considers the potential environmental impact that may result from the use of a new food packaging material. Section 25257.1(c) of the California Health and Safety Code restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other agencies that are consistent with the purposes of the GCI.⁶ Moreover, the SCPA itself requires DTSC to consider the scope of existing laws that protect the safety of the public health and environment, through the relevant exposure pathways. For FCMs, the relevant exposure pathway is oral exposure, which is already fully addressed under the FFDCA. Thus, due to the existing whole chain regulation of FCMs, further regulation under the SCPA would represent regulatory duplication that is prohibited by the GCI and the proposed rules.

⁶ Section 25257.1(c) states, "The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

1. FFDCA Legal Framework

The regulation of food contact materials was established by Congress as part of the 1958 Food Additives Amendments.⁷ These amendments require FDA to regulate food contact materials in the same manner as substances intentionally added to food as ingredients (to the extent that there is any migration or exposure to the components of the packaging). More specifically, Section 201(f) of the FFDCA defines food to mean “articles used for food or drink for man or other animals,” including “articles used for components of any such article” (*i.e.*, food additives). The FFDCA further defines a “food additive,” in Section 201(s), as a substance that is reasonably expected to become a component of food under the intended conditions of use, with certain statutory exceptions.⁸ Thus, to the extent that there is any migration, FDA regulates a food contact material in the same manner as any substance that is directly and intentionally added to food. Food additives, including food contact materials, are subject to premarket authorization by FDA before they can be marketed, unless the use of the substance qualifies for one of the limited exceptions provided under the FFDCA. Accordingly, unless an exemption applies, a person intending to market a new food contact material must first seek clearance from the FDA.

Like substances directly added to food, one of the ways that FDA regulates components of food packaging materials is by the promulgation of food additive regulations, which set forth the conditions under which a particular substance may be used. FDA’s food additive regulations may be found in Title 21 of the Code of Federal Regulations, Parts 170-189. For each of the clearances in these regulations for a food contact substance FDA has conducted a detailed review of the substance’s safety. In addition, as part of its promulgation of a new food additive regulation, FDA (as required by the National Environmental Policy Act⁹) conducts an environmental assessment of the proposed applications to determine if there would be any environmental impact from the manufacture and use of a new substance or whether the use and disposal of the new product would adversely affect the recycling of post-consumer materials.^{10,11}

⁷ Pub. L. No. 85-929, 72 Stat. 1784 (1958).

⁸ As detailed below, examples of substances that are exempt from the definition of food additive include substances that are generally recognized as safe (GRAS) or prior-sanctioned for their intended use by FDA before January 1, 1958.

⁹ 42 U.S.C. §§ 4321 *et seq.*

¹⁰ FDA has published guidance documents discussing the information and data that must be included for its environmental review. *See* FDA, “Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition” (May 2006) at

Congress provided FDA with authorization to use a new regulatory procedure for the review of new food contact substances and new uses of food contact substances when it enacted the Food and Drug Administration Modernization Act of 1997 (FDAMA).¹² FDAMA added Section 409(h) to the FFDCA authorizing the Food Contact Notification (FCN) program. The FCN program has been operational at FDA since 2000, and now FDA reviews the overwhelming majority of food contact substances under this program. Under the FCN program, manufacturers must submit information on the identity and use of the food contact substance, along with information supporting the conclusion that the substance is safe for the intended use. While the system does not result in the promulgation of a new food additive regulation, the safety and environmental evaluation standards are the same as for the food additive petition process. (Arguably, FDA's evaluation of food contact substances under the FCN program is even stricter than it was before the FCN program was available, as the Agency added additional chemistry and toxicity data requirements when it established guidelines for the new program.) If FDA does not object to a manufacturer's FCN, the proposed substance, along with the terms and conditions under which it may be used, is published on FDA's website along with the identity of the notifier.¹³ FCNs are proprietary to the notifier and may only be relied upon by the notifier and its customers. Manufacturers who produce the same material must submit their own notification to FDA.¹⁴

(...continued)

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm> and "Environmental Assessment Technical Assistance Handbook" at

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm084224.htm>.

¹¹ An article describing FDA's food additive approval process and safety evaluation was recently published by the former director of FDA's Center for Food Safety and Applied Nutrition and the former Director of the Office of Food Additive Safety. While the article focuses on food ingredients, *per se*, FDA regulates the safety of food contact materials in a similar manner, thus, the article is instructive of the Agency's safety assessment. See "FDA's food ingredient approval process – Safety assurance based on scientific assessment" A.M. Rulis and J.A. Levitt, *Regulatory Toxicology and Pharmacology* 53 (2009) 20-31.

¹² Public Law No. 105-115, 105th Congress (Nov. 21, 1997).

¹³ Effective notifications are published on FDA's website at <http://www.fda.gov/Food/FoodIngredientsPackaging/FoodContactSubstancesFCS/ucm116567.htm>.

¹⁴ Additional information on the FCN process and FDA's regulation of food contact materials can be found in a recent chapter in a book published by the Food and Drug Law

(continued ...)

Once a material is cleared by FDA, the Agency continues to monitor public information and safety that may question whether the use of the material continues to be safe. Under the FCN, notifiers are required to submit to FDA any new toxicological data or other information that may come to their attention that could affect FDA's decision that the use of the substance is safe.

2. Data Required for FDA's Review

To evaluate the safety and environmental aspects of the use of a new food contact substance, FDA requires a manufacturer to submit extensive data to the Agency. FDA has published guidance documents regarding its requirements for the data and information that must be included in a food additive petition or FCN.¹⁵ These data include:

1. a full chemical description of the food contact substance, its impurity profile, and details regarding its manufacture;
2. information on the technical properties of the substance for its intended use;
3. data demonstrating the amount of the substance that may migrate from the article to food;
4. calculations of the estimated dietary exposure to the substance and its impurities based on its anticipated use;¹⁶

(...continued)

Institute. See D.W. Hill and R.A. Bond, "Chapter 4: Food and Drug Packaging," in the Food and Drug Law Institute's *Food and Drug Law and Regulation* (2011).

¹⁵ FDA, "Preparation of Food Contact Notifications for Food Contact Substances: Toxicology Recommendations" (Sept. 1999, updated Apr. 2002), at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081825.htm> and "Preparation of Food Contact Notifications for Food Contact Substances: Chemistry Recommendations" (Apr. 2002, updated Dec. 2007) at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081818.htm>.

¹⁶ The dietary exposure is calculated by multiplying the amount of a component expected to migrate to food by the approximate fraction of the daily diet expected to contact materials containing the additive. This fraction is known as a "consumption factor." These calculations invariably represent a conservative estimate of the dietary exposure of the additive because they

(continued ...)

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 9

5. all available toxicological data that the notifier has in its possession or that is publicly available must be provided for the substance and its impurities;
6. certain minimum toxicological data, the volume of which depends on the estimated dietary exposure from the proposed use; FDA's tiered requirements for toxicological data for substances with a potential dietary exposure between 0.5 parts per billion (ppb) and 50 ppb mandate two *in vitro* genotoxicity studies demonstrating that the substance is not mutagenic or genotoxic; for substances with dietary exposures above 50 ppb, FDA requires a third genotoxicity study in the form of an *in vivo* chromosomal aberration study, and two subchronic feeding studies, generally one in a rodent species and one in a non-rodent species. For substances with exposures above one part per million in the diet, FDA requires a full panoply of toxicological data, including the data identified above as well as from a chronic two-year bioassay, a one-year feeding study in a non-rodent species, and multigenerational reproductive and developmental toxicity studies. Of course, if any of these studies indicate a hazard trait or toxicological endpoint of concern, FDA may require additional studies to demonstrate that the proposed use will be safe;¹⁷
7. data that allow FDA to consider the potential environmental impact that may result from the clearance of a new food contact material;¹⁸ unless the proposed use of the food- contact substance qualifies for an exemption, petitioners and notifiers must submit information that the proposed manufacture of the food

(...continued)

are based on the assumption that the component will always migrate at maximum levels, and that all food contact materials of a given type will be made using the subject substance.

¹⁷ *Id.* To put these toxicity thresholds into perspective, 1 ppm is equivalent to one drop of water diluted into 50 liters (roughly the fuel tank capacity of a compact car), 1 ppb is equivalent to one drop of water diluted into 250 chemical drums (50 m³), and 1 part per trillion (ppt) is equivalent to one drop of water diluted into 20 Olympic-size swimming pools (50,000 m³).

¹⁸ FDA's categorical exclusions are set forth at 21 C.F.R. §§ 25.30-34. The Agency set forth its rationale for why certain applications are exempt from the need for an environmental assessment in the Federal Register notice promulgating this rule. *See* 62 Fed. Reg. 40569-40600 (July 29, 1997). *See also* FDA, "Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition" (May 2006) at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm081049.htm>

contact substance will not affect compliance with any federal and state environmental laws related to any discharge to the environment, such as air and water emissions.

So, as you can see, the information required for FDA's review is comprehensive, addressing a product's identity, intended use, potential exposure, and safety.

a. Specific Toxicological Information

As discussed above, FCMs are designed to be inert and to not release their components to food or have an effect on the food. The potential transfer of substances from FCMs is, therefore, only likely at very low levels, resulting in negligible exposures. As stated above, this is in contrast to other consumer products for which there are direct exposures at substantially higher levels. Thus, while FDA requires the submission of acute toxicity data when available, the Agency is more concerned with potential carcinogenicity effects or other endpoints from repeated-dose studies. The end points of interest strongly correlate with the hazard traits and toxicological endpoints identified in the SCPA. Section 69502.2 of the SCPA establishes the initial list of Chemicals of Concern based on lists from authoritative organizations, considering seven hazard traits: carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity. As discussed in more detail below, FDA considers all of these toxicological endpoints when evaluating the safety of a food contact substance.

(1) Carcinogenicity

The FFDCa prohibits the use of carcinogenic food additives, including substances used in food contact materials that become components of food. Specifically, Section 409(c)(3)(A) of the Act (also known as the "Delaney Clause") states that no food additive shall be deemed by FDA to be safe if the additive is found "to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of safety of [the additive], to induce cancer in man or animal."¹⁹ Thus, it is not possible to use a substance considered to be a carcinogen that would be a food additive when used in food contact materials.

The Agency has established standards for the presence of any carcinogenic impurities that may be present in food contact materials. The standard that FDA has established for these materials is known as the "constituents policy."²⁰ FDA sets an extremely strict standard for

¹⁹ FFDCa § 409(c)(3)(A); 21 U.S.C. § 348(c)(3)(A).

²⁰ 47 Fed. Reg. 14,464 (Apr. 2, 1982). Although this Advanced Notice of a Proposed Rulemaking was withdrawn by the agency in a November 26, 2004 Federal Register notice (69 Fed. Reg. 68,831, 68,831), the impetus of the withdrawal was administrative only, and FDA

carcinogenic impurities. The Agency uses data from animal carcinogenicity studies, together with extrapolation procedures, to calculate the potential risk from the estimated daily exposure to the carcinogenic impurities as a result of the particular use. In order to determine that there is a reasonable certainty of no harm, FDA requires that the dietary exposure to a carcinogenic impurity must not exceed the calculated upper-bound lifetime risk from all sources of exposure and be lower than a risk of 1 in 1 million.²¹

(2) Reproductive and Developmental Toxicity

FDA requires that reproductive and developmental toxicity data be submitted for substances when the dietary exposure may be significant for these toxicological endpoints. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for reproductive or developmental toxicity, the Agency may request additional data. As with genotoxicity data, any GRAS determination must consider these toxicological endpoints as well. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.²²

(...continued)

has since made clear that the constituents policy remains a valid means by which it evaluates minor carcinogenic impurities of food additives.

²¹ *Id.* at 14,468.

²² In a 1999 paper, Dr. Ian Munro and colleagues established a safety evaluation procedure for use by the Joint Food and Agricultural Organization/World Health Organization of the United Nations (FAO/WHO) for flavoring substances implementing a threshold of toxicological concern approach involving a number of toxicological endpoints. The study authors concluded that “toxicity endpoints, such as developmental toxicity, neurotoxicity, and immunotoxicity demonstrate considerably higher human exposure thresholds than the threshold value [established using carcinogenicity data], making it highly unlikely that these non-cancer endpoints are a relevant concern in applying the threshold concept.” *See also*, Kroes, R., Galli, C., Munro, I., Schiltwe, B., Tran, L.-A., Walker, R., and Würtzen, G. (2000) “Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A Practical Tool for Assessing the Need for Toxicity Testing,” *Food and Chem Toxicol*; 38: 255-312. The Kroes study reviewed an expanded databases to establish if additional toxicological endpoints were more sensitive than the carcinogenic endpoints of a variety of chemical substances. The report indicates that none of the specific non-cancer endpoints (*i.e.*, developmental toxicity, developmental neurotoxicity, and immunotoxicity) was more sensitive than cancer endpoints for the same substances. The results of a more recent analysis were published by Kroes and colleagues in 2004. The authors conclude that, based on their examination of metabolism and accumulation, structural alerts, endocrine disrupting chemicals and specific toxicological

(continued ...)

(3) Genetic Toxicity and Mutagenicity

FDA requires genetic toxicity and mutagenicity testing for any chemical substance with a potential dietary exposure above 0.5 ppb. In addition, if structural alerts suggest that a substance may have genetic or mutagenic attributes, FDA may request that additional data be provided. Any GRAS determination must consider these toxicological endpoints, as well. In the case of materials that do not migrate, there would be no exposure, although the level of analytical sensitivity needed to determine whether the “no migration” threshold would be lower than 50 ppb also is based on these genotoxicity concerns.²³ In our experience, if a substance is determined to be mutagenic or genotoxic in screening tests, FDA will require (a) data demonstrating whether these effects are likely to be observed *in vivo*, (b) a cancer bioassay to resolve whether the material is a carcinogen, or (c) proof that potential dietary exposure will be insignificant even if the material is later determined to be a carcinogen; generally, this would be at a level that would not exceed 50 parts per trillion, 0.05 ppb, in the diet.

(4) Endocrine Disruption

The proper assessment of the endocrine disrupting potential of a particular chemical is a topic of much current discussion. Whether the *in vitro* endocrine disrupting effect exhibited by a chemical at the extremely low doses of oral exposure associated with food packaging actually translates to an adverse physiological effect is in our opinion, at best, very controversial. Moreover, the health effects of chemicals acting through an endocrine mode of action should generally be captured by traditional toxicological tests, which are designed to detect adverse health effects acting through any means, including interaction with the endocrine system.

FDA and other bodies around the world that regulate food contact materials are monitoring current scientific information on this subject. At this time, however, no regulatory body in the world that is responsible for food safety has established separate endocrine disruption

(...continued)

endpoints, including neurotoxicity, teratogenicity, developmental toxicity, and immunotoxicity, carcinogenicity is the most sensitive toxicological endpoint. See Kroes, R., Renwick, A.G., Cheeseman, M., Kleiner, J., Mangelsdorf, I., Piersma, A., Schilter, B., Schlatter, J., van Schothorst, F., Vos, J.G., and Würtzen, G. (2004) “Structure-Based Thresholds of Toxicological Concern (TTC): Guidance for Application to Substances Present at Low Levels in the Diet,” *Food and Chem Toxicol*; 42: 65-83.

²³ The use of 50 ppb in this context is a concentration that could migrate from the package, not a level of dietary exposure. The resultant level of dietary exposure from food is determined by the consumption factor and would be at least an order of magnitude less, or even more in some cases.

data requirements for food contact materials. Instead these regulatory bodies rely on information from reproductive, developmental and other well established, validated toxicology studies to understand the potential health effects of chemicals, regardless of their mode of action. Moreover, there is no one test that can clearly demonstrate whether a substance is an endocrine disruptor; instead, there must be a case by case determination. FDA already addresses this concern as part of its evaluation. Thus, while industry and government continue to monitor this issue, it is our opinion that there is not sufficient scientific information or agreement on the data at the present time to establish endocrine disruption as a regulatory criterion.

(5) Neurotoxicity

FDA can require that neurotoxicity data be submitted for substances when indicated by the subchronic oral toxicity data for a substance and when the dietary exposure may be significant for this toxicological endpoint. If a substance is identified as a potential neurotoxicant, FDA may require additional special neurotoxicity testing designed to confirm and characterize the scope of nervous system involvement and to determine dose-response characteristics. In addition, if structurally similar compounds suggest that a compound may exhibit a concern for neurotoxicity, the Agency may request additional data. Any GRAS determination must consider this toxicological endpoints as part of the GRAS evaluation. In the case of materials that do not migrate, there would be no exposure, and generally this toxicological endpoint is not relevant when the exposures are below 0.5 ppb in the diet.

(6) Bioaccumulation

FDA considers the biopersistence and bioaccumulation of a proposed food contact substance as part of its evaluation of food additive petitions and FCNs. If a substance is suspected of being bioaccumulative, the Agency requires further data on its absorption, distribution, metabolism and elimination to determine the potential bioaccumulation in the body. Any GRAS evaluation of a substance would also take this outcome into account. With regard to the other materials that may not be subject to FDA's review, the Agency considers that a daily exposure of 0.5 ppb in the diet is an insignificant addition to the diet from a cumulative exposure standpoint (except for carcinogens). If a substance is present at levels below 0.5 ppb, its bioaccumulation potential is considered to be insignificant.

b. Specific Environmental Information

The National Environmental Policy Act of 1969 (NEPA) requires FDA to assess the environmental impacts of its decisions regarding the safe use of FCMs. Under FDA regulations, all submissions must be accompanied by either a claim of categorical exclusion or an adequate environmental assessment (EA) to permit FDA to determine whether a clearance for a food contact material may significantly affect the quality of the human environment. As part of its safety evaluation, FDA requires that a food contact substance not have an adverse environmental

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 14

impact during its manufacture, use, and disposal. Any environmental impact that may result from manufacture, use, or disposal, such as aquatic toxicity or toxicity to terrestrial organisms, must be addressed.

Most importantly, because of their inert design there is not likely to be any chemical exposure from a food contact material that could have an adverse effect on the environment at any level of concern. Substances used in food contact materials are trapped within a matrix (*e.g.*, a polymer, coating or paper) and are designed to not leach from the product, thus preventing migration and limiting exposure to low levels. Unlike other substances that are designed to directly come into contact with consumers or their environment, the potential for direct exposure to a substance from a packaging material is very small. The possible levels of migration of a substance from a food contact article are very low, generally in the part per million range or lower. Indeed, FDA has determined that a significant number of submissions for FCMs are categorically excluded from the need for an EA because they do not, individually or cumulatively, have a significant effect on the environment. For other substances, an EA is required.

The EA focuses particularly on the introduction of substances into the environment as a result of the use and disposal of FCMs, the fate of those substances, and the resulting environmental impacts. The evaluation should address not only the food contact material, itself, but also its degradation products, and any other substance resulting from its use and disposal. With regard to the use and disposal of the food contact material, the EA addresses the market penetration, how much will enter the waste stream, the mode and frequency of the disposal, as well as the expected concentration of the potential chemical substances introduced into the environment as a result of the disposal. Information must be submitted that evaluates the potential environmental impact of the disposal, including bioaccumulation, for methods such as landfill leachate and incineration. The extent of the potential environmental impact is determined with reference to the physico-chemical properties and environmental depletion mechanisms for each substance. Finally, any environmental impacts are assessed in relation to their toxicity to laboratory animals, to satisfy human safety requirements, and to organisms that may be exposed in the environment, such as vertebrates, invertebrates, plants, fungi, and bacteria. If adverse environmental impacts are demonstrated, mitigation measures and alternatives must be discussed.

In addition, FDA pays particular concern to any impacts that the proposed use of the substance may have on the ability to recycle post-consumer packaging materials. If there is a concern that the new substance may create problems with the recycling processes currently being used, FDA will require further data and information or limitations to ensure that the proposed use will not create an adverse economical or technical impact on the ability to recycle food packaging materials.

FDA's environmental review for FCMs is thorough, and addresses all of the concerns raised in the GCI. Therefore, requiring FCMs to undergo an environmental review under the SCPA would be duplicative and unnecessary.

3. Exceptions from Premarket Review

As noted above, there are limited exceptions to the need to obtain a food additive regulation or an effective FCN for the proposed use of a new food contact substance. First, FDA may exempt a material from the need for a regulation of FCN under its Threshold of Regulation exemption procedure. FDA's Threshold of Regulation procedure, which is codified at 21 C.F.R. § 170.39, allows the Agency to exempt a substance from the need for a regulation or FCN if the proposed use of the substance meets certain criteria:

1. the substance must not be a carcinogen and may not contain any carcinogenic impurities with a TD₅₀ (*i.e.*, median toxic dose) value less than 6.25 mg/kg body weight per day;²⁴
2. the proposed use of the substance must not result in a dietary exposure exceeding 0.5 ppb or, if the substance is currently regulated for direct use in food, the proposed increase in the dietary exposure must be less than one percent of the established acceptable dietary intake (ADI) for the substance;
3. the substance has no technical effect in the food; and
4. the proposed use of the substance may not have a significant impact on the environment.

FDA adopted the Threshold of Regulation procedure after reviewing a large number of published studies indicating that there was little toxicological concern from the exposure to noncarcinogenic substances at levels below 0.5 ppb in the diet.²⁵ FDA reserves the right to determine if substances qualify for the exemption and provides response to companies submitting such a request.

²⁴ The TD₅₀ is the chronic dose level that would induce tumors in half the test animals at the end of a standard lifetime for the species.

²⁵ 60 *Fed. Reg.* 36595, July 17, 1995. A full report and all of the individual papers written as part of a study examining this issue were published in the August 1990 issue of *Regulatory Toxicology and Pharmacology*. See Munro, "Safety Assessment Procedures for Indirect Food Additives: An Overview," 12 *Regulatory Toxicology and Pharmacology* 2 (August 1990).

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 16

The FFDCA also provides certain exceptions to the definition of a food additive that also apply to food contact materials. Specifically, the Act exempts those materials that are considered to be generally recognized as safe (GRAS) or that were sanctioned by either FDA or the United States Department of Agriculture (USDA) prior to the adoption of the Food Additives Amendment in 1958. Food additives, as well as food contact materials that qualify under these exemptions, are not technically subject to premarket review by FDA, although in many cases companies request FDA's review.

The FFDCA exception for GRAS substances as provided in Section 201(s) states that such a determination requires a general recognition "among experts qualified by scientific training and experience to evaluate [the additive's] safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use." FDA has promulgated regulations setting forth the criteria that the Agency regards as necessary to establish that the use of substance is GRAS. These eligibility requirements provide that a general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. The basis of such views may be either (1) scientific procedures or (2) in the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. General recognition of safety requires common knowledge about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food."²⁶ Moreover, FDA has clarified that "scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation."²⁷ The main toxicological data and other information that support a GRAS determination must be published, generally in peer-reviewed scientific journals.

FDA has a procedure to review and sanction GRAS determinations through a GRAS Notification process.²⁸ In addition, the Agency has listed or affirmed some materials as GRAS in Parts 182, 184, and 186 of the food additive regulations. A determination may be made without FDA's review that a substance is GRAS provided that sufficient published toxicological data exist to establish the general scientific recognition that a substance's use is GRAS. The standards for such a self-determined GRAS assessment are robust. As stated by two former FDA officials, Drs. Alan Rulis and Joseph Levitt, "many people mistakenly associate GRAS with a sort of "second" tier of safety protection based on a less-than rigorous standard compared to

²⁶ 21 C.F.R. § 170.30(a)(2).

²⁷ 21 C.F.R. § 170.30(b).

²⁸ See FDA, GRAS Notification Program, at <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASNotificationProgram/default.htm>.

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 17

petitioned food additives. This is not true. In fact, the safety standard applicable to GRAS food ingredients is the *same* as for food additives; namely reasonable certainty of no harm.²⁹ The former directors went on to say that “[i]n fact, the GRAS criteria are in some ways more difficult to satisfy than the food additive criteria because of the additional requirement of public availability of the data and general recognition and acceptance of a safety conclusion based on those data.”

The FFDCA also expressly exempts those materials that were sanctioned by USDA or FDA in letters issued by these Agencies before the passage of the Food Additive Amendments in 1958. In the experience of our members, the substances covered by prior sanctions and still used in commerce are limited, and many of the substances were subsequently petitioned or notified to the FDA. FDA very strictly interprets previously issued prior sanction letters, and limits the scope of the exclusion by construing prior sanctions as narrowly as possible.³⁰

Substances also may be used without express premarket approval from FDA if they can additionally be shown to not migrate from the food contact article. The standard for this assumption is strictly interpreted by both the Agency and industry. In general, a showing of no migration must be based on an analytical sensitivity demonstrating that there would be no migration at a level equivalent to 50 ppb and often lower in some situations.³¹ The basis of the exclusion from premarket clearance is that, given the very low migration of the substance to food, the resulting dietary exposure among consumers will be negligible.

In sum, the exemptions from premarket approval for food contact materials are strictly limited by the FFDCA. Only those materials that are subject to published toxicological data and generally accepted by the scientific community as safe may be considered to be GRAS and used without FDA review. Those substances covered by prior sanctions are limited, and the substances used in food contact materials that do not migrate to food result in no exposure to consumers. In addition, these substances when used in food contact articles are still subject to FDA regulation under Section 402 of the FFDCA.³² Under no circumstances may any substance cause a health or safety concern when used as intended and may not affect the taste or odor of the food. Thus, it is our opinion that the substances that qualify for these limited exceptions do

²⁹ See A.M. Rulis and J. Levitt, p. 26.

³⁰ See 456 F. Supp. 207, 209 (d. Neb. 1978), *aff'd sub nom. United States v. Nielsen* (8th Cir. 1979), cert. denied 444 U.S. 832 (1979). See also, 21 C.F.R. § 170.38(d).

³¹ The resulting dietary exposure for most food contact substances, even if there were some migration below the level of detection, would be less than 0.5 ppb, a level below FDA's threshold of toxicological concern.

³² 21 U.S.C. § 342(a)

not result in exposures of concern and, therefore, subjecting them to the scope of the GCI would not promote the purposes of the statute. Including such materials within the scope of the GCI will duplicate the existing regulatory scheme which Congress and FDA have established.

C. Summary

FDA has in place a comprehensive and robust system of regulation for food contact materials that establishes a large margin of safety. The regulations proposed by DTSC to implement the GCI would duplicate this system, yet FDA's regulatory scheme is consistent with the purposes of the GCI. Thus, the inclusion of these products in the SCPA would contravene the limitations proscribed by Section 25257.1(c) of the Health and Safety Code and would not promote the safety or environmental goals of the GCI.

III. Potential Consequences of Including FCMs in the SCPA

It is difficult to see any benefit that could come from DTSC's additional regulation of FCMs. Such regulatory duplication would likely result in product deselection rather than an extensive analysis of chemical alternatives because consumers do not have the knowledge to understand the complex scientific analysis that goes into a safety evaluation for a food contact material. Duplication also imposes unnecessary additional administrative and financial costs on both industry and DTSC, and potentially inhibits the development of safer materials. In some cases, this may force the use of packaging that is less proven to be effective in reducing the risk from dangerous food spoilage bacteria. Ultimately, duplication could result in the withdrawal of safe food packaging products from the California market to the detriment of both industry and consumers.

A. Use of a Chemical of Concern is Likely to Result in Product Deselection

The stated goal for the GCI is to enable businesses, consumers, and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products. This goal implicitly assumes that the implementing regulations will ensure a thorough analysis of the chemical in question, how it is used, whether there is the potential for consumer or environmental exposure, and whether there is an alternative chemical to use that would work in the same technical manner, without drastically increasing costs and resulting in a safer product. Practically, however, once a chemical has been identified as a Chemical of Concern many manufacturers will require reformulation or will simply drop the substance because of the likelihood that consumers will no longer buy products containing that chemical. For food packaging, reformulation often is much more complex from a technical or cost perspective and can result in significant trade-offs in the efficacy of a product. FCMs specifically are designed to ensure the safety of food for the entire shelf-life of a product, and reformulation could impact the efficacy of a product, potentially resulting in an increase of foodborne illness. Moreover, recent experience has shown that even a rumored chemical safety concern starts a strong consumer

movement toward deselection of products containing that chemical. It is reasonable to expect, therefore, that once the list of Chemicals of Concern is published, deselection of these products will occur, rather than a reasoned discussion of the safety or the merits of chemical alternatives or the chemical, itself.

The GCI seeks to provide information to consumers to permit informed choices regarding the products they purchase, but the scientific complexity of a safety assessment for FCMs makes it extremely difficult for consumers to evaluate the safety concerns for a packaging material that contains a Chemical of Concern, should they seek to do so. As described above, the evaluation of FCMs requires a substantial amount of information regarding a product's identity, intended use, the potential exposures to the product and any of its components and impurities, and a rigorous safety analysis of those exposures. This evaluation is undertaken by scientists with years of training and experience in chemistry, toxicology, biology, and environmental assessments. Yet the use of a Chemical of Concern in an individual food packaging product may be extremely small, without any reasonable possibility for the substance to become part of food or be exposed to consumers or the environment. Thus, many FCMs, the safety of which has already been established under the existing FDA framework, could be irrationally deselected by consumers on the basis of the presence of one Chemical of Concern. This result is clearly not to the benefit of either industry or California consumers.

B. Including FCM is Administratively and Financially Inefficient

The SCPA establishes substantial burdens on those products that are designated as "Priority Products," including a broad range of evaluation and reporting requirements. We are concerned that the scope of the regulations as proposed will create such an immense administrative and scientific burden on DTSC that it will not be feasible for the Agency to implement. The regulation contains an abundance of new responsibilities for DTSC, many of which require time-consuming and difficult scientific evaluations. We believe that DTSC is not equipped, with financial support or personnel, to administer these responsibilities. As discussed above, the safety evaluation for FCMs is scientifically complex and requires technical knowledge and experience. FDA and industry has invested in countless personnel and resources to ensure that FCMs are safe to bring to market. The GCI product mandate is broad, addressing almost all consumer products on the market. Thus, considering the scientific and technical complexity of evaluating FCMs, DTSC should defer to the reasoned and scientific judgment of FDA, otherwise there will likely be long delays and regulatory uncertainty that is detrimental to industry and consumers. As noted in a recent letter signed by sixteen California legislators and provided to Governor Jerry Brown, ". . . DTSC has the authority to impose a range of unclear regulatory actions from doing nothing to completely banning a particular chemical or product from being sold in the state . . . it is critical that businesses be provided with certainty of future conditions, so as to not discourage job creation in California."

DTSC also should consider that the financial and administrative burden of the alternative analysis process will inhibit technological innovation and the development of safer and more environmentally friendly food packaging materials, as companies divert their resources to California compliance activities rather than research and development of new, safer products. If DTSC implements the SCPA as is, the practical result is likely to be the withdrawal of a substantial number of products from the California market as companies choose to withdraw from the market rather than undertake the costly alternatives analysis requirements when these products have already been subject to review by FDA.

The existing regulatory framework for FCMs is more than sufficient to provide safe products for consumer use. DTSC's duplication of this scheme will almost certainly delay the arrival of safe materials on the market and, ultimately, the extra regulatory compliance costs could even force industry and safe consumer products out of the California market. In this competitive global marketplace, the goals of the GCI should be achieved in the most efficient and least burdensome means possible—in this case, by deferring to the existing, comprehensive, science-based legal and regulatory framework established by the FFDCa and implemented by FDA.

IV. The SCPA is Preempted by Federal Law

Regulating food contact materials under the SCPA is not only barred by the duplication provision of Section 25257.1(c), but also preempted under Federal law. Applying the SCPA to food contact materials would conflict with the FFDCa not only by undermining the goals set by Congress when it enacted the Food Additives Amendment of 1958 ("Amendment"),³³ but also by imposing, on a substance-by-substance basis, regulatory responses like use restrictions that could be directly contrary to FDA requirements. As such, the SCPA, to the extent that food contact materials are not exempted, would be subject to challenge on multiple fronts, both the statute as a whole and as applied to specific substances.

Preemption analysis begins with the Supremacy Clause of the U.S. Constitution, which declares that the "Constitution and the Laws of the United States . . . shall be the supreme Law of the Land."³⁴ As the Supreme Court has stated, "it has been settled that state law that conflicts with federal law is without effect."³⁵ The same holds true of state law that conflicts with federal regulation.³⁶ Courts look specifically to the intent expressed by Congress when adopting a

³³ 21 U.S.C. § 348, *et seq.*

³⁴ *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617 (1992).

³⁵ *Id.*

statute as the “ultimate touchstone” of preemption analysis.³⁷ Such intent may be explicitly stated or implicitly contained in the statute’s structure and purpose.³⁸

While there are various types of preemption, at least one is relevant here – conflict preemption. Specifically, Federal law nullifies conflicting state law in at least two instances. The first type is where state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress” (“obstacle preemption”).³⁹ The second type is where it is “impossible” for a private party to comply with both state and Federal law (“impossibility preemption”).⁴⁰ As discussed below, both forms of conflict preemption would apply in this case absent an exemption for food contact materials.

A. The SCPA Stands As An Obstacle To Reaching FFDCA’s Goals

Under obstacle preemption, courts look specifically to the goals underlying a given regulatory scheme and ask whether the state law would frustrate the Federal agency’s efforts to reach those goals. For example, the U.S. Supreme Court in *Geier* held that an injured motorist’s design defect claim, which sought to hold a car manufacturer liable for failing to install a driver’s side airbag, was preempted. The Court noted that Federal regulations at the time required manufacturers to install passive restraints in “some but not all” of their vehicles and provided a “range of choices among different passive restraint devices” to be “introduced gradually over time.”⁴¹ Citing to comments made by the Department of Transportation (“DoT”) when issuing the regulation, the Court noted that its purpose was to “lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance – all of which would promote [the regulation’s] safety objectives.”⁴² In other words, DoT adopted a compromise between gradually forcing technological development and addressing immediate safety needs. The Court, not surprisingly, found that a state tort law which would require airbags in all vehicles “presented an obstacle to the variety and mix of devices that the federal regulation

(...continued)

³⁶ *Fidelity Fed. Sav. & Loan Ass’n v. De La Cuesta*, 458 U.S. 141, 153 (1982) (“Federal regulations have no less pre-emptive effect than federal statutes”).

³⁷ *Cipollone*, 112 S.Ct. at 2617.

³⁸ *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

³⁹ *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

⁴⁰ *Cipollone*, 112 S.Ct. at 2617.

⁴¹ *Geier* 529 U.S. at 864, 874-75.

⁴² *Id.* at 875.

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg

October 11, 2012

Page 22

sought” and to the “gradual passive restraint phase-in that the federal regulation deliberately imposed.”⁴³

The same conflict exists between the FFDCA and SCPA. It is clear from the Amendment’s legislative history that Congress pursued a carefully considered approach that struck a balance between insuring food safety and encouraging the advancement of food technology. Prior to the Amendment, Congress had become increasingly concerned that Federal law at the time “entirely prohibit[ed] the use of these additives even if their use at safe levels would advance our food technology and increase and improve our food supplies.”⁴⁴ As the Senate Report noted:

The second flaw in existing law which has proved detrimental to consumers, to processors, and to our national economy and which this bill seeks to remove is a provision which has inadvertently served to unnecessarily proscribe the use of additives that could enable the housewife to safely keep food longer, the processor to make it more tasteful and appetizing, and the Nation to make use of advances in technology calculated to increase and improve our food supplies. Your committee agrees with the [FDA] that existing law should be changed to permit the use of such additives as our technological scientists may produce and which may benefit our people and our economy when the proposed usages of such additives are in amounts accepted by the [FDA] as safe.⁴⁵

Indeed, the House Report stated that the “purpose of the legislation is twofold: (1) To protect the health of consumers by requiring manufacturers of food additives and food processors to pretest any potentially unsafe substances which are to be added to food; and (2) to advance food technology by permitting the use of food additives at safe levels.”⁴⁶ This “dual purpose,”

⁴³ *Id.* at 881. See also *In re Bextra*, 2006 WL 2374742, at *9 (N.D. Cal. Aug. 16, 2006) (finding failure to warn tort claims involving an anti-inflammatory drug preempted under the FFDCA where class action plaintiffs argued for warnings that would have upset the policy choice made by FDA to require the disclosure of known risks, but prohibit “defensive” labeling warning of unsubstantiated risks); *Blue Circle Cement, Inc. v. Bd. of County Comm’rs*, 917 F. Supp. 1514, 1519-20 (N.D. Okla. 1995) (holding local ordinance effectively prohibiting the burning of hazardous waste for energy was preempted by the Resource Conservation and Recovery Act’s goal of “replac[ing] land disposal with advanced treatment, recycling, and incineration”).

⁴⁴ H. Rep. No. 2284, at 2 (1958).

⁴⁵ S. Rep. No. 2422, at 2 (1958).

⁴⁶ H. Rep. No. 2284, at 1.

therefore, demonstrates that Congress clearly intended to forge a middle ground, similar to the regulatory approach adopted by the DoT in *Geier*, between emerging technology and an immediate need for food safety.⁴⁷

The SCPA and the proposed regulations if adopted, however, pose a substantial obstacle to achieving and maintaining this compromise between food safety and technology. To begin, the primary purpose of the SCPA – to reduce or completely remove chemicals of concern from consumer products – is antithetical to a Federal scheme that permits the safe use of such substances. Merely listing a food contact material as a chemical of concern, and thus subjecting it to further regulation under the SCPA program, would taint any FDA decision authorizing those in the food industry to use the substance. FDA cannot effectively provide consumer confidence about the safe use of substances and ensure that their benefits are fully realized if, at a minimum, a cloud of future state regulation or an outright ban hangs over certain food contact materials.

Simply being targeted as a chemical of concern under the SCPA, moreover, could lead to a *de facto* ban on the substance. Even where FDA has approved a food contact material as safe for use, regulatory burdens and market pressure resulting from being listed or associated with a priority product could, in effect, result in the removal of a substance from the stream of commerce. For instance, in recent testimony before the DTSC, the National Products Association stated that retailers would likely pull priority products off the shelves rather than incur the expense of compliance.⁴⁸ This is precisely the outcome that Congress intended to avoid when it amended the FFDCFA in 1958—stifling further development of food technology when the substance is otherwise safe to use.

Finally, in the event that DTSC places use restrictions on a specific food contact material, obstacle preemption could be implicated on a substance-by-substance basis, particularly where the state's requirements are more stringent than FDA's. For example, the proposed regulations permit the DTSC to impose “[r]estrictions on the amount or concentration of the Chemical(s) of Concern permitted in a product” and “[a]ny other use restriction that reduces the amount of any Chemical(s) of Concern in the product, or reduces the ability of the product to contribute to or

⁴⁷ See also S. Rep. No. 2422, at 3 (The Amendment “would make possible the use of additives discovered by our scientists which, having been adjudged safe for humans and animals when used in or within certain quantitative limits, could materially advance our ability to make more wholesome foods available to more people at all seasons and, perhaps, we hope, to assure to ourselves and others the ability to stockpile supplies of healthful and appetizing foods over such long periods of time as emergencies might make either desirable or essential.”).

⁴⁸ DTSC, Hearing Transcript, at 53 (Sept. 10, 2012), available at <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

cause an exposure to the Chemical(s) of Concern in the product.”⁴⁹ Similarly, the FDA is authorized under the Amendment to set the maximum quantity of a food contact material that may be used.⁵⁰ However, if DTSC sets a use level more stringent than that deemed safe by FDA, the objectives set forth by Congress, for all practical purposes, will be defeated.⁵¹

B. Regulation Under The SCPA Could Directly Conflict With The FFDCA

Regulation of FCMs under the SCPA could also put manufacturers in a precarious position where it is impossible to comply with both Federal and state law because DTSC’s regulations are not just an obstacle to FDA’s safety determinations, but in fact directly conflict. Under such circumstances, Federal law would prevail.⁵² For instance, FDA regulations limit the types of uses permitted for certain types of food contact materials (for example, see 21 C.F.R. § 176.170 (limiting uses for paper and paperboard that come into contact with aqueous and fatty foods)). Likewise, the proposed regulations allow DTSC to “impose restrictions on the use of one or more Chemicals of Concern . . . in a Priority Product . . . or restrictions on the use of the product itself.”⁵³ This includes the form in which a product is sold and who may purchase or use the product. It is possible, therefore, that FDA and DTSC could limit a substance to entirely different uses. In this instance, if a manufacturer complies with the Federal standard, it would necessarily violate the state limitation, and vice versa. As such, the state regulation would be preempted. Given the extensive authority proposed for DTSC in terms of regulatory responses, including labeling requirements, use restrictions, and outright bans, it would be no surprise if DTSC’s regulatory responses lead to numerous instances of impossibility preemption.

C. Summary

Without an exemption for food contact materials, the SCPA and the regulations, if adopted, would be subject to preemption challenges on a number of levels. Not only would the entire statute and state regulatory scheme be placed into question as they clearly frustrate and undermine the purposes for which Congress adopted the Federal program, DTSC may also face

⁴⁹ SCPA § 69506.5.

⁵⁰ 21 U.S.C. § 348(c)(1)(A).

⁵¹ See, e.g., *Frith v. BIC Corp.*, 863 So. 2d 960, 967 (Miss. 2004) (finding objective preemption where plaintiffs’ design defect claim would have imposed safety requirements for cigarette lighters that were stricter than the federal standard, thus upsetting the balance struck by Federal regulators of “sanctioning child-resistant lighters not too difficult for adult operation”).

⁵² *Cipollone*, 112 S.Ct. at 2617.

⁵³ SCPA § 69506.5.

constant lawsuits seeking to bar regulatory action on individual substances as the agency pushes for restrictive regulatory responses that conflict with FDA requirements. While this would ultimately be a matter for a court to decide, DTSC should be mindful of these considerations when determining its future regulatory actions and not risk the state's resources in litigation that may not be successful.

V. Other Concerns

A. Alternatives Analysis Threshold Exemption

The SCPA includes an exemption from the requirement for a Priority Product to conduct an Alternatives Analysis. For each Chemical of Concern that is the basis for the product being listed as a Priority Product, DTSC must specify an "alternatives analysis threshold;" if that Chemical of Concern is present in the Priority Product at a concentration lower than the established threshold then an alternatives analysis is not required for that product.⁵⁴ For FCMs, the appropriate threshold for safety has already been established by FDA based on a stringent evaluation and FDA's experience. It is difficult to see how and why DTSC would substitute its judgment for FDA's, when the Agency has decades of experience with these types of chemicals and products. Moreover, FDA coordinates with other federal agencies to harmonize the development of safe levels of potential exposure, and to benefit from collective knowledge of many scientists. DTSC does not have the resources and experience to duplicate this system.

All FCMs are evaluated to ensure that they are safe when used as intended. As part of the evaluation, limits may be set on the use of the material, including a limit on the concentration of a chemical. The levels set by FDA are determined based on its thorough scientific review and risk assessments. FDA has over fifty years of experience reviewing and evaluating food contact materials, and employs over thirty people for the specific purpose of evaluating their safety. DTSC has very little experience with evaluating the safety of FCMs, and will not have a staff dedicated solely to these materials. Instead, DTSC will be responsible for scientifically evaluating thousands of chemicals, in hundreds of products from all areas of the market. Thus, as a legal, scientific, and practical matter, DTSC should not be establishing threshold levels for a substance used in a food packaging material; instead, it should defer to FDA.

B. DTSC Should Remove Certain Sources from its "List of Lists"

Several of the primary sources for the "list of lists" from which DTSC will prepare the list of Chemicals of Concern should not be relied upon because they are either based on incomplete scientific evidence or are overinclusive. The SCPA regulations establish an immediate list of Chemicals of Concern based on existing lists of substances with identified

⁵⁴ SCPA § 69503.5.

hazards. Specifically, Section 69502.2(a) lists the twenty-two existing lists that either: (i) list chemicals on the basis of exhibiting at least one of seven hazard traits (carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, and/or persistent bioaccumulative toxicity); or (ii) list chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. Three of these lists—(1) the International Agency for Research on Cancer (IARC) Group 2B substances, (2) the Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, and (3) the National Toxicology Program's (NTP) Monographs on the Potential 16 Human Reproductive and Developmental Effects—should not be relied upon to develop the Chemicals of Concern list. The IARC Group 2B and Category 1 endocrine disruptor sources are lists based on incomplete scientific evidence and are, thus, insufficient as a resource for substances that should be classified as a chemical of concern, while the NTP list is overinclusive because it also lists substances that have been determined to be safe. These three lists were not developed to be lists of hazardous substances and are not an appropriate resource for developing such a list.

1. IARC Group 2B Substances

The IARC Monographs identify environmental factors that can increase the risk of human cancer. The Group 2B substances are those defined as possibly carcinogenic to humans, because there is limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals or when there is inadequate evidence of carcinogenicity in humans but there is sufficient evidence of carcinogenicity in experimental animals. As per IARC guidance, there are a number of issues when evaluating chemicals with “limited evidence of carcinogenicity,” thus, this group should not be used as a list to identify cancer hazards.

For Group 2B substances, a definitive evaluation of cancer hazards cannot be made because (a) the evidence of carcinogenicity is restricted to a single experiment, (b) there are unresolved questions regarding the adequacy of the design, conduct or interpretation of the studies, (c) the agent increases the incidence only of benign neoplasms or lesions of uncertain neoplastic potential, or (d) the evidence of carcinogenicity is restricted to studies that demonstrate only promoting activity in a narrow range of tissues or organs.

By comparison, the IARC list for Group 1 and 2A carcinogens are more reliable and, thus better able to identify substances as hazardous. For inclusion in Group 1, the substance is determined to be carcinogenic to humans and must show “sufficient evidence of carcinogenicity.” To be included in Group 2A, the substance is “probably carcinogenic to humans” and must demonstrate that “a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more

independent studies in one species carried out at different times or in different laboratories or under different protocols. An increased incidence of tumours in both sexes of a single species in a well-conducted study, ideally conducted under Good Laboratory Practices, can also provide sufficient evidence. A single study in one species and sex might be considered to provide sufficient evidence of carcinogenicity when malignant neoplasms occur to an unusual degree with regard to incidence, site, type of tumour or age at onset, or when there are strong findings of tumours at multiple sites.” The standards for listing in Groups 1 and 2A are significantly more stringent than for 2B.

DTSC could potentially be relying on poor science if it includes the Group 2B list. As outlined above, there can be many concerns with the evidence used to classify the substances. More specifically, these concerns include the following:

- High dose animal studies are not relevant to consumer exposure – there is a wide margin of safety between those substances exhibiting a threshold response and the levels to which consumers might be exposed. As discussed above, substances in food contact materials are trapped within the polymer matrix, and migration is expected to occur only at very low levels;
- Tumor type may be isolated to only limited number of target tissues at an incidence that is not considered to be statistically or biologically significant;
- Tumor type may be rodent specific and not relevant to humans as the mode of action may not be plausible or possible in humans;
- Tumor type may be limited to only one sex or in one species (or strain) and be of questionable biological significance;
- Many cancer bioassays are designed to identify hazardous substances that are used in the workplace where direct and repeated exposures are typical. Consumer exposure in the marketplace is many orders of magnitude lower than in the workplace and may only occur sporadically. The chemicals (272 to date) that appear on the IARC 2B list have occupational exposure limits, which are designed to provide an estimate of acceptable daily workplace exposure;
- The route of exposure used in many of the cancer bioassays, such as inhalation (e.g., lung overload as in the case for carbon black and titanium dioxide which are both 2B carcinogens) may not be applicable to the potential exposure in the consumer product; thereby considerably overestimating hazard potential;
- Some chemicals were designated as 2B based on non-standard studies such as non-guideline, very old, and/or do not meet currently acceptable protocols or testing methodology;
- Study results may not be robust or reproducible or consistent with results available for analogues or structurally similar substances;

- For 2B chemicals, there may be some evidence in animal models, but stronger evidence against carcinogenicity from available human epidemiology studies, nonetheless the classification was assigned as ‘possibly’ carcinogenic;
- Data interpretation may vary by investigator (e.g., pathologists may have differing opinion on the tumor incidence, severity, or biological significance); and
- Some studies are not conducted properly such as with using non-concurrent control groups or inappropriate survival rates in control or treatment groups.

For these many reasons, the rationale for including a substance on IARC Group 2B is not a scientifically reliable basis for inclusion on DTSC’s list of Chemicals of Concerns, and this group should be removed from the “list of lists.”

2. Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*

The Category 1 endocrine disruptors identified in *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption* should not be included in the “list of lists” because these substances were identified only on a preliminary basis, and have not been subjected to the rigorous testing necessary to determine whether they truly are Chemicals of Concern. This report was prepared by a consultant for the European Commission, and explicitly states that the report was intended as “a first step towards the establishment, by the Commission, of a priority list of substances for further evaluation of their role in endocrine disruption” (emphasis added).⁵⁵ Indeed, the “working list” of 564 chemicals proposed in the report has been substantially pared down over time, with many substances removed due to insufficient scientific evidence or because they should not have been included in the first place.

This report clearly has been superseded by subsequent chemical evaluations, and should not be included as a scientifically reliable source for Chemicals of Concern. For this reason, we urge DTSC to remove this report from the “list of lists.”

⁵⁵ BKH Consulting Engineers, in association with TNO Nutrition and Food Research, *Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption*, November 10, 2000.

3. NTP Monographs on the Potential 16 Human Reproductive and Developmental Effects

The NTP's monographs on reproductive or developmental toxicants should not be included as a source of Chemicals of Concern because this list includes substances that have been evaluated as having no evidence of adverse effects. The monographs are produced by the NTP's Office of Health Assessment and Translation (OHAT), which is the successor to the Center for the Evaluation of Risks to Human Reproduction (CERHR). CERHR/OHAT monographs classify chemicals based on: (1) the weight of scientific evidence on adverse effects, expressed on a seven-part scale ranging from "clear evidence of adverse effects" to "clear evidence of no adverse effects;" and (2) the agency's level of concern that a chemical is associated with various reproductive and developmental effects, expressed on a five-part scale ranging from "serious concern for adverse effects" to "negligible concern for adverse effects." In the second analysis, the agency may also find that "insufficient hazard and/or exposure data" exists.

A CERHR monograph can therefore determine that a particular chemical presents "clear evidence of no adverse effects" and express "negligible concern for adverse effects," yet the chemical is not removed from the monographs. Thus, a chemical could be qualified as a Chemical of Concern because it was "identified" in a CERHR/OHAT monograph but not present any sort of hazard. We respectfully recommend that these monographs be removed from the potential sources of Chemicals of Concern, or alternatively, that DTSC make clear that only CERHR/OHAT monographs indicating high levels of evidence and concern regarding adverse endocrine effects are considered as the basis for addition to the Chemicals of Concern list.

VI. Conclusion

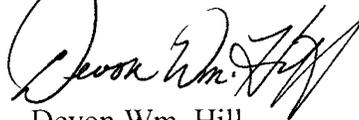
Food packaging is important to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf-life of products to reduce food waste. FDA, under federal law, has established a comprehensive regulatory scheme to ensure the safety of food contact materials, which provides a large margin of safety. This regulatory scheme is consistent with the goals and purposes of the GCI. In the opinion of our members, a separate duplicative regulate scheme would inhibit technological innovation and development that is important to ensure the safety of food and provide consumers with even safer and more environmentally friendly food packaging materials. Thus, the further regulation of food contact materials under the GCI is prohibited by Section 25257.1(c) of the Health and Safety Code.

KELLER AND HECKMAN LLP

Ms. Krysia Von Burg
October 11, 2012
Page 30

For the reasons set forth above, we respectfully request that the DTSC exclude food-contact materials and substances used as components of food-contact materials from the scope of any regulations promulgated to implement the GCI.

Cordially yours,

A handwritten signature in black ink, appearing to read "Devon Wm. Hill". The signature is written in a cursive style with a large initial "D".

Devon Wm. Hill

GCREgs@DTSC

From: Susan France <sue@thewickerworks.com>
Sent: Monday, October 01, 2012 11:27 AM
To: GCREgs@DTSC
Subject: I demand to be protected against chemicals in consumer products!

Categories: Comment

Why is the US so far behind Europe on this issue! I, who only eats organic foods, etc. demand that our representatives protect us from the harmful chemicals in consumer products. Do not let big business destroy our health!

Susan France


From: Garner, Dylan@Waterboards
Sent: Thursday, October 11, 2012 1:59 PM
To: Marxen, Jim@DTSC
Cc: Liao, Marcia@Waterboards
Subject: Potential Error in Public Notice

Hi Jim,

We just spoke on the phone. I think there might be a math error in the DTSC Safer Consumer Products regulations. I would look at the following text:

“There are currently more than 80,000 chemicals approved under federal law for use in the United States (U.S.). Each day, a total of 42 billion pounds of chemical substances are produced or imported in the U.S. for commercial and industrial uses. An additional 1,000 new chemicals are introduced into commerce each year. Approximately one new chemical comes to market every 2.6 seconds, and global chemical production is projected to double every 25 years.”

The text appears on page 3 of the Public Notice. If 1,000 new chemicals are introduced each year, isn't that 2.7 per day? Not sure where the 2.6 per second comes from.

Thanks,
Dylan



August 9, 2012

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

**Comments on California Proposed Regulation R-2011-02 [Safer Consumer Products]
Submitted via email: gcregs@dtsc.ca.gov**

Gradient is a health risk consulting company that does extensive work in the area of consumer product safety and comparative risk assessment. We anticipate working as certified assessors under the Safer Consumer Products program and therefore view ourselves as stakeholders in the regulatory process.

We would like to commend the Department of Toxic Substances Control (DTSC) for the extensive work undertaken to develop the July 2012 regulations. Changes made to the October 2011 regulations increase their flexibility and demonstrate a more collaborative attitude towards the regulated community. There remain a few aspects of the regulations about which we have specific concerns or which appear to be unclear, as described in the following comments.

Section 69501.1 Definitions

(52) Reliable information

Page 12

DTSC states that reliable information "means a scientific study or other information that is one or more of the following:" and includes "(A) Published in a scientifically peer reviewed report or other literature." as one example. While peer review is a reasonable minimal indicator of study quality, the level of peer review differs substantially among journals. The current definition leaves open the possibility that a single poorly designed study, published in a journal with less rigorous review, could be used to petition DTSC for action based on "reliable information." This highlights the need for DTSC to incorporate information concerning Weight-of-Evidence analyses under the definition of "reliable information." Based on the current wording of the regulation it is not clear if DTSC would consider a single study published in a peer reviewed journal as sufficient evidence for initiating some sort of regulatory decision under the SCP regulations. We would suggest that the definition include a statement that in determining whether information is reliable, DTSC will consider such factors as the appropriateness of the data collection and analysis methods employed, the size of the study population (if applicable), and/or the relevance of the experimental system to the question being addressed.

Section 69502.2 Chemicals of Concern Identification

Page 24

The text states that in determining whether to list a chemical as a Chemical of Concern (COC), the department may consider the availability of safer alternative chemicals. It would be helpful to provide some indication of where this *a priori* knowledge might come from. Clearly, the process of conducting an alternatives analysis (which follows as a result of the listing) will indicate whether an alternative exists. Would DTSC's determination be based on an alternatives analysis that has previously been submitted for similar products?

Section 69503.2 Priority Products Prioritization Factors

Page 25

We support DTSC's decision to not include shared mode of action as a basis for considering adverse impacts. For many chemicals the situation will be complex (e.g., possibly involving multiple overlapping modes of action) and not fully elucidated. Mode of action is also likely to be highly dose-dependent, a particular concern when dealing with exposures to consumer products and complex matrices. Using mode of action as a consideration would add unnecessary uncertainty and controversy to any COC analysis.

Section 69503.2 Priority Products Prioritization Factors

Page 25

It is not clear why "physical chemical hazards" (d) are mentioned specifically when hazard traits (which should include physical hazards) are already included under (a).

Section 69503.2 Priority Products Prioritization Factors

Page 27

We strongly support DTSC's decision to give greater priority (all other factors being equal) to products where there are more data to substantiate adverse impacts and exposures. We would suggest that it should not be just a "greater amount of information" but a "greater degree of reliable high quality information."

Section 69503.4 Priority Products List

Page 29

Subparagraph 2 introduces the concept of a highly durable product and gives limits on the number of chemical components that can be specified per product. Subparagraph 4 states these limitations do not apply to products designed or intended primarily for children 12 years of age or younger or to products intended to be worn on the body or that may be dispersed as an aerosol or vapor or result in runoff or volatilization. It is not clear to the reader why such products are singled out for exemption from the limits described in Subparagraph 2. Perhaps some discussion of this could be included in any accompanying explanatory text?

Section 69503.5 Alternatives Analysis Threshold Exemption

Page 32

We support the idea of a product-specific threshold rather than an across the board chemical specific threshold because it allows for greater consideration of potential exposure factors. At the same time, we recognize the new system will create more uncertainty for the regulated community and the general public. The advantage of the prior system was that when a chemical was placed on the COC list, it would be immediately clear to manufacturers or importers whether their product had a low enough concentration to avoid designation as a priority product. Under the new system, the manufacturer/importer remains uncertain until DTSC takes some action on their specific type of product. Products containing designated COCs at any level may also be a source of public concern that is unfounded. DTSC must therefore stress in public communications that the mere presence of a COC in a product does not equate to a health or environmental hazard.

We are also concerned about the impact of matrix effects on the ability to detect chemicals in different types of materials. Unlike environmental media such as soil, groundwater or air, consumer products involve complex matrices with substantial problems in terms of reliably detecting specific chemicals at low levels. We urge DTSC to work closely with product

manufacturers and/or their suppliers to establish thresholds that can be reliably and economically tested.

In addition, section (c) (3) appears to state that the DTSC can set a threshold below the analytical detection limit based on considerations such as inherent toxicological potency, bioaccumulative potential or detection in biological tissues (*i.e.*, "notwithstanding paragraph 2A" which specifies the detection limit as the minimum value for the threshold). How can a threshold below the achievable detection limit serve as a screening criterion for conducting alternatives analysis in any practical way?

Section 69503.5 Alternatives Analysis Threshold Exemption

Page 32

In part (e), the last part of this section, we would suggest including the term "reliable" as used elsewhere in the regulations (*i.e.*, "...based on new, or newly considered *reliable* information").

Section 69508.1 Qualifications for Accreditation Bodies

Page 68

Subparagraph (a)(5) (A) (3) refers to "toxicology atmospheric chemistry". We assume a comma is missing. Because this subparagraph refers to ecological effects, we would suggest "ecological toxicology" or "ecotoxicology" be used to better distinguish from subparagraph (a)(5)(F) "toxicology and comparative risk assessment".

We would also suggest the extensive list of teaching competencies for accreditation bodies include basic statistics and methods for critically evaluating scientific studies. Currently, critical evaluation is only included for epidemiology studies, (a)(5)(D)(2), but critical evaluation of many types of studies (*e.g.*, chemistry, toxicology and exposure/biomonitoring studies) will also be critical to conducting a valid alternatives analysis.

Thank you for this opportunity to provide comments on this important new set of regulations. If you require additional information, please feel free to contact me at (206) 267-2924.

Sincerely,



Thomas A. Lewandowski, MPH, Ph.D., DABT
Principal Scientist
Gradient
tlewandowski@gradientcorp.com

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)



Principles of Alternatives Assessment

An industry coalition has come together to collect the following recommendations on how alternatives assessment should be conducted based on industry's vast experience designing, manufacturing and marketing thousands of safe and successful products to billions of consumers around the world.¹ This coalition recognizes the importance of a pragmatic and science-based approach to alternatives assessment and offers the product development and improvement paradigm as the basis for an appropriate framework².

Alternatives assessment (AA) is core to developing safe consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs and preferences, is the ability of manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is a fundamental component of the product design process. The product improvement process is iterative, complex, and different on a product-by-product, company-by-company, and case-by-case basis. Additionally, two manufacturers performing an alternatives assessment on the same product will likely reach differing but equally valid conclusions owing to their innovative and technical skills. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful framework for alternatives assessment. Product safety and industry best practices were

A sensible approach for conducting an alternatives assessment is flexible, modular (focusing on relevant parameters), effective, ensures consumer acceptance, ensures informed decision-making, allows for gradual and measured implementation, and includes a feasibility check.

¹ The industry coalition consists of staff and member-company experts from the Grocery Manufacturers Association, American Chemistry Council, American Cleaning Institute, Consumer Specialty Products Association, International Fragrance Association North America, Personal Care Products Council, Research Institute of Fragrance Materials, and Toy Industry Association.

² "Alternative Analysis III: Industry Practices in Product Research and Development, an Alternative Analysis" (September 15, 2011) - <http://dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/GCSymposiumAAllI.cfm>.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Definition of Alternatives Assessment

AA whether mandatory or voluntary should be a flexible but rigorous process adapted from the product development process that considers a number of design, performance, manufacturing, health and environmental impact, and consumer acceptance factors in identifying and analyzing potential improvements to an existing product. AA has a multitude of additional applications or uses beyond simply evaluating substitutes for chemicals/technologies of high concern.

Component Modules of an Alternatives Assessment (AAs)

- Policy incentives should be implemented that recognize companies who voluntarily seek “safer” alternatives, and should serve as the primary tool that states use in promoting safer alternatives or green chemistry innovation without the need for a third-party approach.
- When conducting alternatives assessments “commercial viability” of each alternative should be evaluated. This might incorporate components of regulatory compliance and manufacturing compatibility along with commercial availability and cost effectiveness, among other factors.
- For high profile alternatives assessments, external stakeholder involvement may be warranted to minimize miscommunications with the public. However, stakeholder involvement in internal business design decisions would likely be very rare. Environmental justice (EJ), occupational concerns and related social considerations should be integrated into many of the product development steps. A number of social, worker and EJ considerations may be aspirational that companies wish to address but are external to their business decisions. It may be more appropriate to tier AAs to encompass essential elements and aspirational elements, with those that are able to address the aspirational elements attaining higher classification (e.g., LEED-type ratings: Silver status vs. Gold status).

Initial Evaluation

- Manufacturers should regularly evaluate the life cycle maturity of their products that may dictate the extent to which a product is re-engineered or redesigned.
- Principles of Green Chemistry and Green Engineering are good sources when evaluating product design and development.
 - <http://pubs.acs.org/doi/pdf/10.1021/es032373g>
 - http://www.epa.gov/oppt/greenengineering/pubs/basic_info.html

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Identification of Alternatives

- A chemical may have multiple functions in a product and may require multiple changes in ingredients and manufacturing to adequately satisfy those functions.
- There should be a recognition that alternatives need to be “technologically and commercially feasible.” Therefore, following brainstorming, there might be some initial judgments regarding whether an alternative warrants further investigation based on technological and commercial feasibility.
- Most manufacturing entities will be largely dependent upon material suppliers for information regarding potential alternatives to specific chemicals. This close relationship permits the product design process, something that is typically very sensitive within a company, to be conducted in a confidential fashion.
- For public alternative assessment exercises there are a number of “crowd-sourcing type” tools to engage a larger community of experts and other stakeholders:
 - The US government has a crowd-sourcing website (www.challenge.gov) where a problem is put out to the public for solutions. In addition, there are private firms in the business of facilitating crowd-sourced solutions such as IdeaScale (www.ideascale.com).
 - Another means of generating (new) alternatives is through the creation of a source of recognition of an innovation. However, recognition should not be an end in itself, but one means within a broader strategy for spurring change and to provide innovation support process. Among the kinds of recognitions that could be used are:
 - Exemplar prize (such as the Nobel Prize): defines excellence within an area.
 - Point solution prize: aims to reward and spur development of solutions for a particular, well-defined problem (NASA for example, for forecasting solar activity, keeping food fresh in space, and developing a compact aerobic device for astronauts); akin to the crowdsourcing described above, and to include financial incentives to successful adoption of the solution.
 - Exposition prize: helps identify and promote a broad range of promising ideas and practices that may not otherwise attract attention.
 - Network prize: builds networks and strengthens communities by organizing winners into new problem-solving communities that can deliver more impact than individual efforts.
 - Participation prize: creates value during and after the competition – not through conferral of the prize award itself but through their role in encouraging contestants to change their behavior or develop new skills that may have beneficial effects during and beyond the competition.
 - Market stimulation prize: attempts to establish the viability of a market to address a potential market failure, mobilize additional human talent and financial capital to jumpstart development of a new industry, or change perceptions about what is possible.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Hazard Assessment

Hazard assessment of alternatives will be a fundamental component of an alternatives assessment. However, any comparative assessment methodology that relies solely on hazard can be grossly misleading and may result in unintended consequences. Comparative hazard assessment is but one factor in a multi-factorial evaluation.

- The hazard assessment should focus on the collection of hazard information for the chemical(s) being evaluated and any potential alternatives. It may be possible to characterize an alternative based on the hazard information, but it is premature to eliminate an alternative solely on this basis without consideration of the use, exposure, performance, availability and other relevant factors.
- Clear and consistent criteria should be established for the sources of data that will be collected and used. Information should meet specific data quality criteria for inclusion into the assessment.
- Hazard data is often binary (typically, inclusion, or not, on a list for a particular endpoint, for example, carcinogenicity) or a continuum (such as a particular toxicity value or bioaccumulation value). In either case, the quality of the data reported will dictate its utility. Furthermore, data quality can often be used as a discriminator for cases where there are multiple results available.
 - Selection of data sources should be consistent with internationally recognized definitions for reliable information such as that from the Organization for Economic Cooperation and Development (OECD): "Reliable information" is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ("QSAR") approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by OECD in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies."
(http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1_00.html)
- There are a number of widely accepted tools for filling data needs including the use of molecular similarity, read across, and a number of computational methods. Adequately validated tools should be utilized during the hazard data gathering phase.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Exposure considerations

Consideration of exposure potential is an essential factor for any chemical or product evaluation.

- First, there should be a reasonable or foreseeable route of exposure to the subject chemical before there is a need to conduct an alternatives assessment.
- Second, indicators of potential exposure may be useful in initial screening or prioritization efforts, but additional information such as use patterns, levels in products above an appropriate *de minimis*³, and product forms should inform the exposure evaluation. Both chemical mass and corresponding physicochemical properties, as well as the route of exposure, are useful in assessing relative impact. This is also an opportunity to factor in sensitivities of unique subpopulations.
- Third, potential for exposure will help identify and eliminate alternatives that may likely adversely contribute to significant exposure through use.

Prior to any required alternatives assessment, the source(s)/major contributor(s) to overall exposure would have to be identified. While biomonitoring data may be helpful as supplemental information, it is well-established that the presence of a chemical in biomonitoring studies does not necessarily indicate there is a likelihood of harm. As stated by the Center for Disease Control and Prevention (CDC), “The measurement of an environmental chemical in a person’s blood or urine is an indication of exposure; it does not by itself mean that the chemical causes disease or an adverse effect.”

(<http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf>) In an analogous manner, environmental monitoring may provide additional information to inform the risk assessment, but does not necessarily reflect levels of concern in an organism. There must be a realization that reliable methodologies will not necessarily be available to detect and measure certain chemicals in a particular human tissue matrix. Assuming measurement is possible, mere detection or even measurable levels may not contribute to an adverse impact. Lastly, biomonitoring reflects aggregate exposure to a particular compound at the time of analysis that may fluctuate depending on the toxicokinetic profile of the chemical.

It is important to note that all factors, not limited to simply exposure, must be considered together. Intended use would identify relevant exposure pathways worth evaluating further for relevant human health and environmental impacts. Exposure is also considered during the lifecycle of the product, evaluating risk at each stage (e.g., occupational).

³ Whether a chemical is an intentionally-added ingredient or a trace contaminant may impact how a *de minimis* threshold is established.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Performance

Performance and how product performance relates to use patterns are key factors which must be considered when evaluating various alternatives. In fact, any alternative must maintain if not improve the level of performance of the product. Substitution of one material with another may have unintended consequences, such as replacing with a less effective chemical, thereby potentially creating a greater exposure despite having a lower hazard, while increasing the overall likelihood of harm. Likewise, reduced performance could result in increased safety concerns from other hazards due to product failure. By focusing on chemical safety alone, one may be led to replace a material with another which has lower physical safety performance thereby creating another type of hazard, as is the case when substituting plastic containers with glass.

Performance is a key element of a holistic approach to safety. Proper exposure and risk assessments are essential tools for evaluating substitutes based on targeted or desired performance features.

Performance criteria are necessary to ensure the level of efficacy/functionality built into the alternative product is met or exceeded. Alternatives assessment evaluators must consider the intended function of the final product. Efficacy/functionality standards may either be prescribed for in regulations or desired by consumers, e.g., antimicrobial log reductions in FDA Over-the-Counter drug monographs v. hair colorant vibrancy and longevity attributes, respectively. Required performance levels may be stipulated in existing regulations, and must be recognized (e.g., drug actives, pesticide actives). Companies cannot simply substitute out of those ingredients. Similarly, companies must consider consumer habits and practices of a “performing” product, characterized in terms of exposure and safety to ensure that use instructions provided are followed accordingly. Use performance assessment, e.g., in-home use test, is critical to evaluating the effectiveness and commercial viability of a product. Cost plays a role in determining the effectiveness of a product as well. Cost-prohibitive materials may diminish the likelihood of finding a viable alternative.

To innovate one or more technically feasible and economically and functionally viable alternatives, a safety profile comparison of the base and alternative together with information on other relevant factors must be developed, and market research for consumer acceptance must be done. A selected alternative must have acceptable or enhanced performance while reducing or eliminating the potential for harm, via reasonable and foreseeable routes of exposure from a product.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

Commercial availability and cost effectiveness

The product development process requires the expending of substantial resources, which hopefully results in a reasonable return on investment. Return on investment must be acknowledged as a critical component of the AA. Innovation requires resources (i.e., people, finances, and equipment) and time (anywhere from months to years) depending on the size of the project and complexity of the product⁴. Feasibility of processing, compatibility and stability requirements, and scalability must be evaluated. Additional special testing for specific claims or consumer tolerance in use may also extend the timeframe needed.

Not only is research and development necessary, but regulatory requirements must also be satisfied. It may be necessary to get a new chemical listed on the EPA Toxic Substances Control Act (TSCA) inventory, by submitting a Pre-Manufacturing Notification (PMN), in order for it to be manufactured in the US.

There are numerous economic trade-offs that must be weighed carefully before moving ahead with any particular alternative. Without careful consideration, one may inappropriately conflate direct experience of ingredient availability with reputation of the ingredient:

- The origination of raw materials may impact costs. For example, due to biodiversity (e.g., plants, flora, fauna native to certain regions for esoteric oils/fragrances), commercial availability comes into question (e.g., fees paid to indigenous tribes to source the raw materials). There may be negative impacts on biodiversity (e.g., encouraging large-scale manufacturing of ingredient A may impede on or have negative impact on native species - flora/fauna).⁵
- UN Treaty on Biodiversity - Availability of material may be controlled by an originating country, which can be unpredictable.
- Economic trade-offs could arise when the raw material might have to be sourced from different regions of the world and , fair trade practices need to be factored in.
- Pricing availability of indirect ingredients on ingredient of interest - Diverting materials from one market to another can lead to an imbalance. For example, tallow may be used as a renewable feedstock for biodiesel fuel thus pulling tallow out of the consumer

⁴ For example, for a "simple" substitution in formulated products, a company at a MINIMUM would need two months to get scientists & engineers coordinated and in the lab; one year of research to find a material that meets safety and economic requirements, supply, etc. ; three months of process lab testing; six months for testing at the manufacturing plant (to include scheduling for an experiment since plants typically run at capacity); three months of consumer testing (note that not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). From the time one or a few materials are identified for further assessment, on the optimistic side, AT LEAST 26 months is necessary for R&D and this is ONLY IF an EPA Pre-Manufacturing Notification (PMN) is NOT required. Realistically, a responsible entity should be given 3 years, with the option to extend for another 2 years, plus an additional 1 year if a new chemical PMN is required (as the PMN work may sometimes be done with an R&D exemption).

However, in most cases, substitutions will be much more complex, and the product system may be more complex. Many substitutions will likely require multiple materials to be substituted for the one chemical of concern. A good example is the replacement of phosphate in auto dishwashing (ADW) products. While some companies continue to optimize the formula on phosphate replacement in ADW over the past 25 years, the initial replacement was accomplished in three years. Phosphate replacement required 4 to 5 different chemicals depending on the formulation, in which one of the materials required a PMN (and a New Substance Notification (NSN) in Canada), and another material an NSN. (Each PMN requires 2-5 years of testing, evaluation, report writing and submission. Examples of other PMNs include: DTDMAC to DEEDMAC in liquid softener replacement, DTDMAAMS to ethanol, Quat in dryer sheet softener replacement, anionic surfactant LAS replaced with HSAS in coldwater detergent.)

⁵ Historical examples include the use of ambergris as a fixative in cosmetics, having a negative impact on sperm whale populations.

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

supply chain, thereby resulting in dislocation of glycerin pricing. It is important to recognize the potential dislocation on the larger market place.

- Production availability for substitutes beyond batch or consumer processing – i.e., capacity for substitution (cost-prohibitive), and quality of materials – should be understood and is an issue with new ingredients especially.

Stakeholder Involvement

Appropriate stakeholder communication is critical and requires providing consumers with accurate and useful information. Published results should be contextualized and communicated appropriately. Industry practices include: posting information on a company's websites; communicating via advertising; packaging; and, a variety of publication channels. It is critical that consumer research is used to understand needs and conveys the information in a manner that is understandable to the consumer/user. However, manufacturers should not be expected to subject their critical business decisions to external entities.

Stakeholder involvement may include: (i) Stakeholders in Performance Assessment and (ii) Stakeholders in the AA process.

(i) Stakeholders in Performance Assessment:

Manufacturers ultimately perform market research to assess consumer preference. Second to that is consumer contact information (e.g., toll free numbers), which is meaningful in identifying critical flaws. Marketers communicate with consumers through a variety of media including websites and 1-800 numbers as well as social media platforms such as Facebook and Twitter. Communications channels provide an opportunity to engage directly with those using the products, give consumers a forum to ask questions about appropriate use, and provide comments on the products.

(ii) Stakeholders in the AA process (including government, NGOs):

The quality of stakeholder engagement and input, substantiated by valid scientific principles, is imperative to appropriate stakeholder communication/involvement.

Social, worker and environmental justice and other related concerns

Hazard Communication and Safety Data Sheets

Manufacturers are developing and marketing products in the US that are safe for human health and the environment. Manufacturers are regularly applying green chemistry and green engineering principles in their operations. At the core of the consumer product industry practices is the essential belief that products, packaging and operations are safe for employees, consumers and the environment within the context of their intended use and good manufacturing practices. Manufacturers/marketers additionally recognize reasonably anticipated misuse. By implementing the principles of green chemistry, complying with applicable laws and regulations and continuing to innovate, critical environmental, social and worker justice issues would inevitably be addressed. While green chemistry can contribute to achieving greater sustainability, green chemistry programs must recognize the interplay between hazard and exposure rather than take an extreme precautionary approach.

Manufacturers, distributors, retailers, employers and employees have shared responsibility for hazard communication, training, and appropriate handling of chemicals. It is important to

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

acknowledge OSHA requirements (now aligned with the Globally Harmonized System for Classification and Labelling of Chemicals) to disclose health, physical, and environmental hazards, as well as precautionary measures and first aid, on Safety Data Sheets (SDS). SDS are an important component of the Hazardous Communication Standard designed to communicate chemical hazards to promote worker safety. In addition, OSHA requires employee training that must be conducted at the time of initial assignment, and upon introduction of a new physical or health hazard in the environment.

Manufacturers/marketers also acknowledge that there is potential for worker exposure in industrial/institutional/commercial use of products. These uses expect a partnership between user businesses and the manufacturer. The manufacturer has the responsibility to provide adequate information for safe storage, handling and use of materials at their facilities. Because of the additional training and communication responsibilities of the user business, exposure mitigation strategies can be included in the strategy for acceptable use.

Social Benefits and Consumer Acceptance

Inherent in the demand for the products are social benefits. Delivering these social benefits are among the performance assessment requirements that must be included in the evaluation of any alternatives. The consumer expects the alternative product to meet real and perceived benefits.

Environmental justice is a concern of the manufacturers of products that might be subject to alternatives assessment. Substantiation of an environmental justice benefit must be based on a comparison of any alternative against the base case product for any future manufacture and sale.

Sourcing from a part of the world that may be flagged as “conflict materials” or experiencing a “civil war” – is a social justice concern. There are even some jurisdictions that do not invest in certain parts of the world.⁶

There are known and positive social values associated with products on the market. People are using these products for clear benefits; otherwise there would be no market for the products. Maintaining existing product benefits, for example public health benefits such as hygiene, are an important part of alternatives assessment. Diminishing the value of hygiene in cleaning products through substitution would be compromising public health and clearly unacceptable. The inherent benefits of a product must be carefully considered prior to embarking on an alternatives assessment. Focusing too narrowly on hazard, may pull in other real rather than theoretical concerns.

Life Cycle Consideration and Material flow assessment

Lifecycle thinking goes into the material flow assessment. A life cycle screening exercise can be used before going into a complete ISO-compliant life cycle assessment (LCA) as necessary.

Alternative assessments that examine impacts using a material flow assessment often give the most comprehensive look at the opportunities to identify areas of improvement: reducing energy; emissions; and/or raw materials throughout the product development cycle. Every

⁶ For example, <http://info.venkel.com/news/bid/47912/US-Cities-Aiming-To-Become-Conflict-Mineral-Free>

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

product has different impacts during its life cycle phases – from raw material extraction, manufacturing production, distribution, transportation, use/operation and maintenance, recycling and final waste management after its useful life. This analysis, when combined with product development criteria like source reduction and cost reduction, is part of an iterative process of sustainable product design. A material flow assessment approach to product development is the key to developing sustainable products.

As life cycle thinking is used in the material flow assessment, the review of material flow must be adjusted to a performance equivalent basis. This will assure that maximum efficiency of material flow includes flexible alternatives for a holistic comparison of alternatives.

Manufacturers engage in continuous alternatives assessment and product improvement. Life cycle assessment (LCA) is one important tool to assist in optimizing the trade-offs of energy, raw materials and emissions before a product comes to market. This methodology not only provides a multi-parameter look at all the environmental, safety and health impacts of a product system from “cradle to grave”, but also provides a mechanism to identify product improvement – a “what if” analysis. The ISO 14040 standards for LCA, along with the development of commodity LCA databases for most processes and raw materials, make it viable for small, medium and large enterprises to perform screening versions of a LCA, or if necessary, conduct a full life cycle study. Common LCA impacts that are part of a full analysis may include ecotoxicity, human toxicity, acidification, eutrophication, energy use, water use, to name a few.

There should also be consideration of unintended impacts should resource volumes increase due to demand for a successful alternative. An example of this unintended effect is the environmental impact of palm oil cultivation on endangered species habitat due to the conversion from petroleum to “renewable” bio-based feedstocks such as palm oil. Consideration of unintended impacts enables regulators and manufacturers, to have a comprehensive review of alternatives, without shifting to the unanticipated risk.

Decision making methodology

A successful alternatives assessment program should not stifle innovation, but, instead, promote and encourage the development and use of safer alternatives. Such an approach must allow the development of innovative technologies that foster the concepts of green chemistry while also protecting intellectual property rights and trade secrets. Moreover, “trade-off” issues must be carefully weighed.

Additionally, flexibility rather than imposed command-and-control will result in successful outcomes. Manufacturers contract with society to develop products with demonstrated needs over time through iterative processes. Regulators must recognize that they are not in the business of manufacturing products, but in the business of ensuring the public is safeguarded. As such, regulators must recognize the existing societal contracts between the manufacturers of chemicals and products and must not force business decisions. Regulators must allow the marketplace to provide feedback and to foster appropriate decisions regarding product acceptance.

Alternatives assessment guidelines must provide adequate flexibility to accommodate business models of companies from individual start-ups to global operators. Decisions should be based on sound scientific risk assessment to protect human health and the environment, taking into

October 8, 2012

Please direct questions to Maia Jack (202-639-5922, MJack@gmaonline.org)

consideration all of the life-cycle phases. Decision principles must focus on whether alternatives are safer for human health and the environment, meet consumer needs, comply with all local, state and federal laws and regulations, and address significant lifecycle impacts. Final decisions should balance human health and environmental impacts and lifecycle impacts based on risk.

Business considerations, such as supply chain economics, corporate positioning and brand equity will impact each firms decisions. There will not be a single best alternative that works for every manufacturer of a given product, and governments must not impose such requirements.

The product development and improvement methodology has demonstrated success in industry. This is a team approach that includes a variety of disciplines with weighted responsibilities in contributing to the overall success. It sharply contrasts with the command-and-control approach of typical regulatory policy. Thus, if government agencies are to enter into the process, a new approach to public/private partnership with clear responsibilities delineated is required.

Conclusion

In summary, an alternatives assessment should be science-based, evaluating all relevant factors when assessing viable alternatives to an existing product, and ensuring safety. No single factor can be evaluated in isolation from other relevant factors. A sensible approach for conducting alternatives assessment is one that is flexible, modular (focusing on relevant factors), effective, ensures consumer acceptance, ensures informed decision-making, allows for gradual and measured implementation, and includes a feasibility check.



Green Chemistry Alliance

Committed to Product Sustainability in the Global Economy

Alliance of Automobile
Manufacturers

October 11, 2012

American Chemistry Council

American Cleaning Institute

American Forest & Paper
Association

California Chamber
of Commerce

California League of Food
Processors

California Manufacturers
& Technology Association

California Paint Council

California Restaurant
Association

California Retailers Association

Can Manufacturers Institute

Chemical Industry Council of
California

Citizens for Fire Safety Institute

Consumer Healthcare Products
Association

Consumer Specialty Products
Association

Grocery Manufacturers
Association

Industrial Environmental
Association

Metal Finishing Associations of
Northern and Southern CA

National Paint and Coatings
Association

Personal Care Products Council

Plumbing Manufacturers
Institute

TechAmerica

Toy Industry Association

Western Plant Health
Association

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of
Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-
0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the Green Chemistry Alliance (GCA) and its coalition members, we respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

GCA appreciates the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system and we acknowledge that progress has been made. However, while applauding Director Raphael's commitment to the development of a practical, meaningful, and legally defensible regulation GCA observes nevertheless that the proposed regulation, for numerous reasons identified briefly below and in detail by our coalition members, falls well short of those objectives.

GCA is a highly diverse coalition comprised of national and state trade associations and numerous large and small companies spanning the consumer market and global supply chain. For the last four years and eight iterations, GCA and its coalition members have largely coalesced around major aspects of the process and the offered solutions. However, at the request of our coalition members, we are deferring to them to provide a more detailed critique of the regulation and offer their own sector-specific solutions to address their concerns. DTSC must be mindful of the unique issues these industries have identified in complying with the proposed regulatory program.

While the business community appreciates the goal of California's Green Chemistry Initiative of significantly reducing adverse impact to human health and the environment – and, in fact, many of our founding members supported the 2008 enacting legislation on the presumption that the framework would be couched in scientific principles and analysis, and trade secrets would be adequately protected.

GCA and its members unfortunately remain concerned that the proposed regulatory framework:

- will undermine industry's ability to manufacture and/or supply safe products;
- does not establish a predictable, clear, and science-based process that would otherwise identify true priorities that may benefit from an alternatives assessment and ultimate reformulation; and
- provides little assurance that a company's confidential business information will be appropriately protected.

Although conversations with the Department leave one with a feeling of confidence that the proposed regulation is sound and workable, a closer review of the actual language reveals serious gaps in the practical, meaningful and legally defensible manner in which the Department says it intends to implement the program. Further, the latitude which the Department reserves for itself to implement the program is particularly troubling and could result in a much less reasonable program with onerous consequences. It is largely to these excesses of discretion reserved by the Department that the majority of GCA's comments and those of our coalition members are directed. These concerns not only question the practicality, meaning, and legality of the regulation, but also raise issues regarding the necessity, clarity, and consistency of various components of the regulation.

The Department has opted to focus the program initially by identifying up to five Priority Products. While this is a practical approach that will enable the Department to pilot this unique program, learn what works and does not work, and make adjustments accordingly, it is not a panacea as the identification and prioritization of a single product-chemical combination could result a multitude of individual brands being responsive to the regulation. Further, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products. It is difficult to reconcile the complexity of the draft with the marginal improvement in health and environmental safety it is likely to advance. Moreover, full implementation of the regulation as drafted would necessitate a substantial budget requirement for a huge new government bureaucracy.

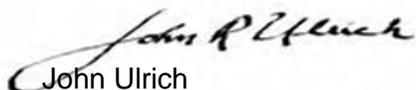
Despite limiting itself to an initial listing of a maximum of five Priority Product/Chemical of Concern combinations, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct this initial phase and far in excess of that which its own resources can sustain. As such, GCA and its coalition members strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. Further, the intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. GCA and its members are concerned the proposed regulation will create an unpredictable framework which will increase uncertainty in the business community regarding compliance, threaten vital intellectual property, and stifle innovation

GCA has long held that in order to implement a workable, science-based program a comprehensive solution to the shortcomings of the regulations must be found rather than simply addressing one or two concerns at the expense of the others. Because of the sequenced nature of this regulatory program each regulatory steps builds off the preceding step. It is critically important, therefore, in order to avoid compounding errors that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Unfortunately, it is this piecemeal approach to addressing concerns which has continued to create tremendous uncertainty and a lack of clarity within the regulated community as it relates to these regulations.

We believe a more focused approach to the regulation could address many of the practical problems raised by the scope and complexity of the draft. .

We appreciate your consideration of our concerns. For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. You may also visit the GCA website at www.greenchemistryalliance.org. Thank you!

Sincerely,



John Ulrich
Co-Chair
Chemical Industry Council of California



Dawn Koepke
Co-Chair
McHugh, Koepke & Associates

Attachment

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

Safer Consumer Product Alternatives Regulation Green Chemistry Alliance Key Concerns

ARTICLE 2. CHEMICALS OF CONCERN IDENTIFICATION PROCESS

According to the requirements in the enacting statutes (AB 1879, 2008; SB 509, 2008), the first step of the regulation implementation must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute GCA firmly believes the prioritization and evaluation process must be based on exposure as well as hazard, and it must avoid duplication and conflicting regulatory requirements.

DTSC's proposed regulation proposes, however, to use a list-of-lists approach to select Chemicals of Concern (CoC) and in doing so focuses on 22 source lists that result in well over 4,000 distinct chemicals that could be considered CoCs purely by their association with these lists and the fashion in which the Department references them in the regulation. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed and is inconsistent with the requirements of the enacting statute unless it is further refined to provide for a subsequent prioritization step to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** Failure of the Department to do this is inconsistent with other state, federal and international regulatory programs that review, assess and prioritize chemicals for regulatory purposes. No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.

In addition to being inconsistent with other regulatory programs, the approach is not practical, meaningful or legally defensible. There are several major concerns with this approach:

- The statute requires that DTSC establish a process to prioritize chemicals of concern, however, the proposed approach performs no prioritization, and thus is not legally defensible.
- Lists are developed for varied purposes. Merging them with no prioritization for the Department's specific purpose results in the identification of items that are not meaningful and have no place in a chemical of concern list—oxygen, nitrogen, iron, aluminum, silver, exotic species, contraceptives, marijuana smoke, viruses, salted fish, wood dust, sediment, and others. Each of these items is relevant to the purpose of the contributing list, but irrelevant to the regulation.
- While listing 4000 or 1200 chemicals may give the appearance of providing expansive public protection, in fact it creates a meaningless, untargeted and low-resolution creation. Nearly 50% of the over 4000 substances are not even on the TSCA inventory making them illegal in US commerce¹; More than 80% were not reported as manufactured or imported into the US in EPA's most recent update; and 90% are not used in consumer products.

¹ Not all chemicals have to be included on the TSCA inventory: chemicals which are used in pesticides and in FDA-regulated products do not have to be registered under TSCA, however most are.

- The identification of all or a portion of chemicals on the 22 lists does not meet the statutory mandate to consider hazard and exposure, nor even the Department's own criteria for adding new chemicals to the list, which requires an analysis of available reliable information on both hazard (adverse impacts) and exposure.
- The establishment of a non-credible list of 4,000 or even 1200 substances will become irrelevant and do little to motivate broad-based action by manufacturers. It is so overwhelming that it will have the opposite effect—more likely, all except those immediately involved in selected Priority Product/Chemical of Concern pairs will take a wait and see approach. Under this approach, if everything is of the greatest concern than nothing is.

To address these concerns and ensure the regulation for identifying and prioritizing CoCs is consistent with other regulatory programs, is practical, meaningful and legally defensible, GCA supports a two-step approach that would prioritize the chemicals as “chemicals under consideration” and “chemicals of concern.” DTSC should then be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others.

Numerous jurisdictions have implemented such an approach, identifying longer lists of chemicals with no direct regulatory implications and that may be considered in the future and then going on to identify much shorter focused lists that do have direct regulatory implications and that are the focus for current action. DTSC has identified many of these in an exhibit circulated with the regulations “COC Lists Around the Globe,” noting “Broad Lists” and “Current Focused Lists” in a number of jurisdictions. However, the exhibit does not appropriately characterize the “Broad Lists”, which in nearly every case have no regulatory implications. Quite the contrary, the proposed regulation subjects DTSC's Broad List of 1200 COCs to direct regulatory implication.

GCA and its coalition members' proposed identification and prioritization approach can be done quickly without diverting DTSC's other efforts to implement the regulation. Further, it produces a large list of “chemicals under consideration” that can serve as a broader marketplace signal, any one of which can readily be moved to a chemical of concern if it is placed into consumer products. It also produces a narrowed and targeted list of chemicals of concern not just to support DTSC's further work, but that will be more likely to prompt action in the marketplace beyond just DTSC's selected CoC/Priority Products. There may also be benefits beyond California in that it will more likely have influence in other states and at the federal level, in contrast to the existing proposed approach naming thousands of chemicals, which will have no impact.

ARTICLE 3. CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS

Under the proposed regulation, priority products containing chemicals of concern are designated through a non-quantitative product prioritization process – otherwise deemed by the Department as a “narrative process.” GCA appreciates a number of changes that have been made from the prior drafts and urges the Department to include them in the final regulation. Specifically, we support

- the process considering both hazard and exposure in setting priorities;
- references to “potential” being removed to better focus on real health and environmental concerns;
- the tightening of the Key Prioritization Factors and requiring that Priority Product/CoC pairs must meet both criteria; and
- the concept of a Priority Product Workplan outlining the Department’s direction for three year periods.

While these changes are for the betterment of the regulation, we remain concerned that the proposed product prioritization process continues to be problematic in a number of ways.

First, the factors in (a) are very broad-based and important; however, the focus in the exposure criteria often seems to be merely on “presence,” “contact” and “occurrence,” which are not the same as exposure. This suggests an entirely qualitative evaluation that could seriously compromise good science-driven decisions. While qualitative information can be helpful, it cannot be used to determine whether a situation presents and exposure with potential for adverse impacts. Presence does not equate to significance, therefore quantitative information demonstrating exposures at levels of concern must be a primary driving factor in priority setting decisions

Second, GCA supports the Department’s approach to identify Key Prioritization Criteria; however, the criteria are employed as an afterthought in the process, and only “reviewed for consistency.” Instead, they should be applied as the critical prioritization process step after evaluations have occurred to determine whether a product/chemical combination is a high priority. If they are not used for the critical prioritization step, then product prioritization becomes an entirely arbitrary process.

Finally, the current proposal has abandoned any focus on intentional ingredients, those chemicals purposefully included in a product to perform a function. The program should be focused in this way to ensure it is meaningful and practical. Chasing unintentional trace levels will significantly diminish the public health and environmental benefits of the program and is impractical. Further, GCA is highly concerned about the lack of a clear and consistent process in the regulation for DTSC to establish an AA Threshold. GCA has consistently advocated that the “safer alternatives” regulations should only apply to intentionally added ingredients that serve a functional purpose at or above 0.1%, consistent with many other state, federal and international systems by which manufacturers are currently regulated. GCA has further advocated for a refinement, not unlike that in the European Classification, Labeling and Packaging (CLP) directive, that for some chemicals on a case-by-case basis a lower or higher concentration be identified by authorities based on a risk assessment. This is largely consistent with the approach to develop Proposition 65 chemical specific exposure thresholds in “no significant risk levels” (NSRL). The GCA has supported this type of refinement on a case-by-case basis for intentionally added ingredients as a practical and consistent approach for the regulation.

ARTICLE 5. ALTERNATIVES ANALYSIS

The alternatives analysis (AA) process is essential for developing safe and innovative consumer products. More and more, the principles of the process are becoming fundamental to the manner in which companies develop products in a sustainability-focused realm. Protecting public health and the environment are inherent components of product design.

Importantly, the product improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A rational, structured and predictable alternatives analysis process that takes these considerations into account is essential from a business perspective. It is important that the Department not “pick and choose” between AAs and mandate a particular alternative, but rather evaluate AAs to ensure that they meet the statutory requirements. A manufacturer should be deemed to have met their statutory obligation when an adequate AA has been completed.

While some of the underlying themes within the proposed draft regulations are appropriate and appear to be consistent with the existing product development paradigm, there remain many challenges and opportunities for improvements to help maintain focus of any required Alternatives Analysis.

- The timeframe described for preparing Alternatives Analysis reports is unreasonable and unworkable should there either be a need to do further experimental research to evaluate a particular alternative or be a desire for a consortium or public-private partnership approach to accomplishing the AA work.
- A single CoC should serve as the basis for designating a product as priority and for the Alternative Analysis process to ensure a workable, pragmatic and meaningful program. As currently written, there is no limitation on the number of CoCs that could serve as the basis for designating a given product as priority.
- The AA should focus on relevant factors and set aside irrelevant ones which will have limited to no significant and meaningful impact on the outcome.
- The scope of the alternatives analysis is broadened substantially when multimedia life cycle impact and chemical hazard considerations are being requested not only for the CoC and its potential substitutes but also for all chemical ingredients known to be in the Priority Product and the alternatives. The focus of any alternatives analysis should be limited to the CoCs in question. If the AA takes on this greatly expanded focus it would seem that manufacturers would have to analyze for all chemicals they use in their products for all factors. This would result in a completely unnecessary waste of resources, moving away from a focused analysis on the most relevant parameters of the alternatives to the CoC.
- A manufacturer’s operating margin is not a good choice as a criterion for the definition and determination of a “technically and economically feasible alternative.” This economic feasibility should be focused on the impact of the alternative on the cost to produce a product.
- As currently drafted, if a responsible entity compares the economic impacts of potential alternatives and the priority product and chooses to retain the priority product, the responsible entity will be faced with difficult challenges to evaluate both direct and indirect cost impacts. More clear and concrete criteria need to be established by which the regulated entity understands what is required to satisfy this provision. The current methods to assess these costs are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well-being of Californians or their environment.
- All of the product development thought process is required to be disclosed. These decisions are value judgments, the fundamental underpinnings of business innovation and are different from company to company. Assurances regarding the protection of this sensitive trade secret information by the Department are lacking in the current proposal.

While there are notable improvements, the alternatives assessment requirements remain highly onerous and lack clarity in a number of sections. While a large company may be able to adapt to the regulations and its requirements, small and medium sized companies, which are the engines for economic growth, will be crippled by the burdens of conducting Alternatives Assessments in order to continue selling safe and legal products in the state.

ARTICLE 6. REGULATORY RESPONSES

The imposition of regulatory responses have the potential of making products unacceptable to consumers or imposing such cost that a manufacturer may cease making the product available in California. The consequences of imposing substantial cost or forcing the withdrawal of products for sale in California are so significant that the various regulatory responses should be imposed only under circumstances that are necessary to carry out the purposes of the underlying statute. GCA is highly concerned that a number of the regulatory provisions lack clarity or exceed the scope of the statute and should therefore be removed or modified to be consistent with the law.

As an example, the proposed regulation provides that the Department shall identify and require implementation of regulatory responses that “maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.” It specifically provides that in selecting regulatory responses, the Department shall give preference to responses “providing the greatest level of inherent protection.” GCA is highly concerned that these provisions conflict with the statutory provision in section 25253. There, the Legislature has established the standard for evaluating chemicals of concern in consumer products and their potential alternatives “to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.” Limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection.

As it relates to the section providing for no regulatory response, it allows for this response action if the Department determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts. Perhaps the Department believes that referring to preventing or limiting public health and environmental impacts is an adequate standard, but the truth of the matter is that it is little more than a redundancy. That is, no regulatory response is required if the Department determines that no regulatory response is required. This section lacks clarity in failing to spell out the standards for this regulatory response.

Finally, as an example, the proposed regulation provides that the Department may impose one or more regulatory responses specified in the preceding sections to situations other than those specified in those sections. As noted before, many of those sections lack clarity regarding the situations that would trigger this particular regulatory response. This response action confers complete discretion on the Department itself to impose any regulatory response under any set of circumstances that it may choose. The Department goes on to say that the Department may periodically reevaluate any regulatory response to determine if changes are needed based upon changed circumstances or information. This section epitomizes the lack of clarity and consistency associated with the proposed regulation.

REGULATORY TREADMILL

The result of this uncertainty associated with the regulation as currently drafted could conceivably result in a product-chemical combination being placed on a regulatory treadmill without significant improvement to public health or the environment. As written, a priority product is identified based on a CoC(s) selected by the Department. That CoC/priority product pair will undergo an alternatives analysis to identify potential alternatives. Even after replacing the CoC with an acceptable alternative, the product is still a priority product forever. Having focused on the product for several years, the Department will be biased to continue focusing on the Alternative Product to prioritize it again as a priority product.

If a priority product is indeed subject to the regulatory treadmill as a result of the current proposal, it will kill innovation, diverting company resources to continuously assess a product that is already safe, preventing the development of other improvements in safety, cost and sustainability. Companies devote substantial resources to ensure the safety of their products, with intentionally-added chemicals and incidental contaminants well below a safe threshold level. We urge the Department to narrow their focus on CoC/priority product pairs that truly contribute to significant adverse impacts on public health and the environment, and for which an alternatives analysis would be beneficial and would improve the safety profile for public health and the environment. When definitive results have been achieved, the Department should no longer consider that product a priority product; instead DTSC should move on to other priority product/CoC combinations.

As we heard at the December 2011 legislative oversight hearing on Green Chemistry, Dr. George Daston with Procter & Gamble commented that “definitive results” would be a successful criterion, without the need for further regulation of the alternative. The Department should endeavor to craft a regulation to meet this goal – we aren’t there yet with this proposed regulation.

ARTICLE 8. ACCREDITATION BODIES AND CERTIFIED ASSESSORS

Accreditation Bodies

Academic knowledge in various fields, without significant experience in formulation, processing, or manufacturing consumer products does not provide sufficient knowledge to become accredited to train and certify assessors. If these entities do not include a wide range of expertise from product and chemical manufacturers, then they may never appreciate the intricacies of product development and R&D and be able to convey the nuances inherent in product development within specific industry sectors to applicants. In many cases those conducting an AA will have significantly more experience than the accreditation body, a case which could lead to significant issues when there are disagreements.

GCA feels strongly that the proposed accreditation program is unnecessary. We are not convinced that such a bureaucratic structure will provide better assessor training when company expertise will still be the core of determining better alternatives as they’ve done for decades. Due to the complex nature of any AA, the availability and accessibility to a wide range of expertise in various scientific fields are instrumental to a successful accreditation body. Broad skills and knowledge are required to conduct analysis across the extremely broad spectrum of products, chemicals, evaluation factors and impacts that would need to be

assessed in AAs as envisioned by this regulation. In addition to key technical skills such as toxicology, environmental toxicology, chemistry, chemical engineering, and microbiology, experience and knowledge of exposure assessment, finance/accounting, life cycle analysis, and consumer and clinical testing will also be required to develop safe and effective products for consumer use.

In this regard, GCA believes the accreditation program proposed would be better suited to helping develop guidelines for conducting an AA and to provide additional training to DTSC in areas where staff members are not already experts.

Certified Assessors

In-house company experts with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead alternative analysis projects for product development and should not have to become certified assessors, or should be certified with minimal requirements based on their experience. An R&D scientist must consider a variety of factors in the selection of chemical ingredients for a consumer product. The safety of an individual chemical and life cycle considerations are only pieces of the equation. Chemical ingredients often serve multiple functions in a consumer product formulation rather than provide a single benefit. Therefore, alternative analysis is a broad process that must evaluate a number of holistic considerations for any potential chemical alternative, including impact on safety and product performance, potential interaction with other formula components, useful life, other environmental criteria, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right combination of chemical ingredients for consumer product formulations. In-house company experts appreciate the intricate R&D science invested in developing consumer product formulations and have the necessary in-depth understanding of consumer behavior and preferences.

DTSC is under the mistaken notion that academic training alone can provide sufficient knowledge for a person to be able to either conduct or lead a robust alternative assessment. The mere two years of professional experience required under the regulation is not nearly enough to be fully aware of the intricacies of formulating consumer products. Further, post-graduate work in the performance of AA's absolutely cannot substitute for the two years of professional experience. Significant experience in the laboratory is typically required for a formulator to know how to develop formulations that are stable and safe for several years, provide the benefits expected by consumers at a cost that they can afford, and then apply that to new ingredients. Five to ten years of experience working as a formulator or processing engineer in a company making consumer products should be the minimum experience required, along with significant experience and training in project management. Global companies may also not have the correct academic and accreditation requirements as required by DTSC; global companies will likely have to rely on global formulation teams based outside the United States. As such, the final regulations will need to have the requisite flexibility to accept the qualifications from around the globe.

The proposed Article 8 assessor training and certification programs are also far too ambitious. To successfully develop a product for the consumer market requires the melding of many different skills, including chemistry, chemical engineering, packaging engineering, microbiology, toxicology, environmental toxicology, manufacturing, quality, occupational safety, finance, consumer insight (psychology, for example), marketing and more. The requirement that one person, especially one with so little real experience in formulation chemistry, to show expertise in all these fields is just not possible. Companies typically retain PhD's in many of

these fields; they are experts in their respective fields and have many years of experience and knowledge in that field, but not in other facets of formulation. Developing and bringing a safe and successful product to market is the result of the combined efforts of these experts plus years of experience in making it all come together.

For many global companies the AA's will be conducted outside of the U.S.; California must make it possible for assessors to come from any geographic location.

If a certified assessor is hired by a company to conduct the AA that company also has to ensure that the assessor is bound by strict confidentiality requirements. The assessor, to do the job adequately, will not only have to obtain confidential information about formulations but also the manufacturing and supply chain capability of the company.

Ultimately, certification should be invested in those individuals charged with overseeing the various aspects of the alternatives analysis and with ensuring successful execution in meeting the Department's requirements. As discussed, an in-house certified assessor is well positioned to understand how to apply an AA to a Chemical of Concern/Priority Product pairing, with a variety of available experts utilized to address specific aspects of the AA. Product development experience should play a significant role in the time and effort necessary for certification.

ARTICLE 10. TRADE SECRET PROTECTION

The proposal as currently drafted threatens vital intellectual property upon which innovation is based by requiring submission of information that is unnecessary, and allowing the Department absolute discretion to make a decision about a trade secret claim.

Further, an unintended consequence of the lack of protection of competitively sensitive information in the draft regulation will arguably result in anticompetitive behavior through the exchange of competitively sensitive information between and among competitors. The exchange of such information between and among market competitors as called for in the regulation was not contemplated by AB 1879 or SB 509. Because the authorizing legislation does not clearly articulate a state policy to impede or impair the competitive process in the manufacture, supply or distribution of Priority Products, any conduct proposed by the draft regulation which has the effect of impeding or impairing such competition would expose industry participants to liability under applicable federal antitrust laws.

More specifically, the proposed regulation provides that the section on trade secret protection "does not apply to hazardous trait submissions for chemicals and chemical ingredients pursuant to this article." This subdivision specifically says that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trait submission or any chemical identity information associated with a hazard trait submission. **This portion of the regulation, however, exceeds the scope of the statutory authority precluding protection for hazard trait submission but not chemical identity.**

REGULATORY DUPLICATION

The applicability of the proposed regulation is overly broad. As written, these regulations enable the Department to regulate almost any product for any use. At best, this is potentially redundant with medical device, food and drug, and occupational health and safety rules, but

could possibly create conflicts with devices or products that are regulated under other authorities.

Under the proposed regulation, regulatory duplication provisions of the statute are not considered until the product prioritization section and again at the regulatory response section of the regulation. Further, it gives the Department the discretion to determine the adequacy of the regulatory requirements currently in place as they compare to the breadth of the Safer Consumer Products regulation's review. This discretion was not intended by the Legislature, authorized by the statute under SB 509 (Simitian, 2008), nor is it necessary. Rather, it is an example of regulatory overreach, suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. This is not a question of the breadth or sufficiency of current regulatory authority and its implementation. Again, the statute under SB 509 (Simitian, 2008; Health & Safety Code §25257.1(b) and (c)) is clear on the matter, with two applicable provisions:

- (b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.
- (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

The proposed regulation goes beyond the statute to assert Department dominance where it believes it would provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were not listed as a Priority Product. It is essential that any applicability of the Safer Consumer Products regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently reviewed. In this regard, regulatory duplication for any product should be an upfront and straightforward question in the applicability stage of the regulation – is the potential health or environmental impact from the chemical in the product reviewed by another regulatory agency or not? Completing the listing, prioritization, analysis and regulatory response of a product and/or chemical that is already regulated is a waste of limited Department resources and fails to meet the practical standard the Department and Director are seeking. Further, where that is the case, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

ECONOMIC ANALYSIS

While the Department filed the Std. Form 399, as required under the Administrative Procedures Act (APA), it was woefully inadequate and devoid of any substantive information. The recurring theme throughout the document is that the economic and fiscal impact of the proposed regulation will only be quantifiable after the regulation is implemented and operating. Given that the Department has afforded the proposed regulation "landmark" status, the document is even more inadequate. DTSC appears to have failed to even attempt to provide any meaningful quantification, choosing instead to rely on questionable document "Economic Analysis for California's Green Chemistry Regulations for Safer Consumer Products" prepared by Matthew E. Kahn.

The entire tone of the economic analysis negatively portrays industry with unsubstantiated generalizations that characterize industry as "profit seeking" with "agendas" that do not align with the spirit and intent of the regulations. Much of the economic and social benefits that are purported to arise from the implementation of the proposed regulations are based on the

supposition that industry does not currently take responsibility for the composition and safety of its products. These assertions are inaccurate, and offensive to responsible manufacturers of consumer products.

DTSC has subsequently indicated in press statements and letters to the legislature that upon adoption of the regulations it intends to conduct economic analyses consistent with SB 617 (Calderon, 2011) on designated Priority Product/CoC combinations, but nowhere in the preparation of Form 399 is that point explicitly announced. Additionally, conducting economic analyses after adoption of the regulation is a bit like “fire – ready – aim.” Additionally there are no explicit provisions in the regulation as drafted to require such an analysis, much less suggest how or to what extent a case-by-case economic analysis pursuant to SB 617 would influence DTSC’s ultimate decisions or requirement to continue through the process if the economic impact is not commensurate with the public health and environmental benefit to be derived from sending it through the process.

GCA cannot help but observe that the issues we have noted above and over the years in previously filed comments, regarding lack of focus, lack of exemptions, excessive listings of chemicals of concern, narrative prioritization processes, lack of quantification and standards, regulatory duplication, compromised trade secrets, and unfettered discretion on the part of the DTSC staff are all a part of the unstated underlying impediments which the Department would suggest prevent a quantifiable economic impact analysis of the regulation as proposed. Still DTSC is resistant to constrain the program. Following this logic one might suggest that any program too complicated to assess should be allowed to proceed.

The inability of DTSC to provide a comprehensive analysis would in GCA’s opinion confirm the legitimacy of industry claims regarding what we believe to be an overly broad and out of control proposal for the regulatory implementation of AB 1879 and SB 509. We urge DTSC to reevaluate GCA proposals and recommendations and adopt same in order to facilitate a full and effective implementation of the enabling legislation

CEQA ANALYSIS

GCA must object to DTSC’s preparation of a draft Notice of Exemption (NOE) without having performed any meaningful environmental review of the “project” as required pursuant to the California Environmental Quality Act (CEQA).

The intent of CEQA as provided by the Legislature under California Public Resources Code Sections 21000 and 21001 provides that it is the policy of California to:

(f) Require governmental agencies at all levels to develop standards and procedures necessary to protect environment quality.

(g) Require governmental agencies at all levels to consider qualitative factors as well as economic and technical factors and long-term benefits and costs, in addition to short-term benefits and costs and to consider alternatives to proposed actions affecting the environment.

However, DTSC’s position with respect to the proposed regulation does not comport with either of these policies, as evidenced by its claim that the rulemaking is exempt from CEQA. DTSC has provided no adequate basis to support its claim that the rulemaking is exempt from CEQA.

While the Department claims the proposed regulations are exempt from CEQA because the structure of the regulation will ensure that there are no adverse environmental impacts associated with any action taken, the proposed regulation contains no mechanism that will ensure compliance with CEQA even at the “project” level.

Unquestionably, the proposed regulation represents a massive program with the potential to fundamentally alter the availability, composition, and nature of consumer products in California. The Department, in fact, has conceded this point in a number of places. For example, in the

Public Notice DTSC states:

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, and are sold, offered for sale, distributed, supplied, or manufactured in California....

Further, the Department’s own press release quotes the Director saying:

We see this as a two-for-one initiative. Public health and the environment benefits by lessening our use of toxic chemicals, and California companies get a significant boost into markets that are rapidly expanding. This regulation will stimulate growth in those markets and move us toward a higher level of environmental protection.

These statements provide direct acknowledgement by the Department that the regulation will affect the environment as well as the fact that there will be short- and long-term impacts – all of which must be more thoroughly considered. When read in the context of the legislative intent set forth in CEQA, these as well as a number of other Departmental statements make it clear that this rulemaking is not exempt from CEQA compliance. Yet, DTSC has performed no analysis, economic assessment, or other review of how affected stakeholders will respond to the regulation.

Bottom line – the regulation should not be adopted without in-depth consideration of all of the factors contemplated under CEQA. The Legislature intended that this type of rulemaking be subject to CEQA; failure to do so is not legally defensible, one of the key goals of the Department and Director in implementing the regulation.

#



October 11, 2012

Attn: Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
gcregs@dtsc.ca.gov

Re: Comments on Proposed Regulations - Safer Consumer Product Alternatives

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

GMA appreciates the opportunity to submit the following comments in response to DTSC's July 2012 Proposed Regulations for Safer Consumer Product Alternatives. We recognize the extensive DTSC staff efforts that have gone into these revisions from the 2011 and early 2012 efforts. In particular, we appreciate and strongly support Director Raphael's direction to make the Safer Consumer Products regulation practical, meaningful and legally defensible. Applying and balancing these concepts can be a pathway to achieving the Green Chemistry Initiative's objectives.

GMA filed substantial comments to previous iterations of the regulations, which we incorporate by reference here. (For a copy of those comments, please see: <http://www.gmaonline.org/issues-policy/product-safety/chemicals-management/green-chemistry/state-comments/>).

The latest iteration of the proposed regulations contains a number of strategic choices that will help in creating a program to improve public health and the environment for all Californians:

- The proposed regulations describe an approach that the Department indicates will identify approximately 185 Chemicals of Concern for the initial focus in the program through 2016. GMA strongly supports the concept behind this approach, which uses information on chemical hazard together with indicators of exposure to narrow the field. This is a critically important step forward, highlighting a core group of substances to make progress on in the initial years of the program, while sending an important signal to the marketplace.
- DTSC indicates that in the first round it will select up to 5 Priority Product (PP)/Chemical of Concern (CoC) pairs. GMA has advocated for and supports this approach to enable focused learning and building on success in the initial stages of implementation.
- DTSC's approach to the AA process is described as "mandating the question" (i.e., the Department picks Priority Products/CoC pairs), not "dictating the answer" (i.e., the

Department does not select the alternative). Rather, companies are expected to conduct the Alternative Analysis and reach their own decisions on product changes.

- The Alternative Analysis (AA) section has some important improvements as well as features that are critical to maintain: the ability for a company to propose an alternate AA process that meets the intent and outcomes of DTSC's AA process; the flexibility to use any appropriate AA methodology and tools; the capability to focus the AA on relevant factors, case-by-case; the absence of 3rd party verification together with the ability to use in-house expertise in developing AA's; the ability to submit an abridged AA report if a functionally acceptable alternative is not available; the flexibility to fulfill some requirements by using a consortium, avoiding potential anti-trust issues; and the ability to eliminate alternatives for 'showstopper' reasons in Stage 1.
- On data requirements, DTSC has chosen to allow submitters to provide quantitative and qualitative information. Where information is lacking, there will be no obligation to fill data gaps initially. However, as a regulatory response, the Department may require the data should there be remaining concerns. This option would allow for timely completion of AA's, and focus any new data requirements on truly critical information needs.

However, there are numerous serious concerns in the proposal that if not addressed will prevent the overall program from being a deliberate science-based effort, focused on real improvements in the safety of consumer products, thus not achieving its full potential. Several continuing and new scientific concerns raise key issues. Additionally, some aspects of the proposal will not only be impractical and unworkable, but may stifle innovation due to the potential for a regulatory treadmill and may result in arbitrary decisions. Beyond these, the regulations will impose unnecessary costs and administrative burdens on companies doing business in California and will require a large DTSC staff to manage the paperwork and process, even if the number of products is limited. The following are some issues of major concern to GMA, addressed more fully in the attached detailed comments:

- The proposed regulation ignores compliance with the strong statutory language prohibiting DTSC from duplicating or superseding other regulations.
- The proposed regulations would impose significant burdens on businesses that import their products into California, which vastly outweigh any purported legitimate benefit.
- Inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure" together with the absence of emphasis on weight of evidence evaluation, but rather the dependence on "most protective" and "greater amount of information" violates standard scientific approaches used in California, US and International regulatory programs. This will preclude the potential for California Green Chemistry's program from building a reputation as a meaningful, science-based program
- The proposed CEQA Exemption and Economic and Fiscal Impact analyses are inadequate.
- This proposal moves away from the focus on consumer products in previous drafts, expanding to include commercial products, bulk chemicals and manufacturing operations and the focus on workers, and including them in the definition of 'sensitive subpopulations'. Those are not the intended objective of the statute.
- The proposal would establish a chemical of concern list from chemicals on 22 lists that contain well over 4000 chemicals. DTSC indicates that the chemical of concern list will be narrowed to 1200, but does not disclose the process for doing so. However, 4000 or

even 1200 chemicals of concern do not provide a useful focus for the program and will have no benefit in the marketplace. Given the initial focused set of approximately 185 chemicals, the 1200 should instead be described as 'Chemicals of Interest'.

- The non-quantitative product prioritization process, a so-called 'narrative process', as proposed is not suitable for identifying high priorities that will make meaningful improvements to public health and the environment in California.
- The addition of a confusing and unnecessary new term – "homogeneous material" – in addition to existing overlapping, confusing and non-standard definitions for "chemical", "chemical ingredient", "component", and "consumer product/product" further complicates the entire regulation.
- "AA Threshold Concentration", which replaces the previous *de minimis* terminology, is unscientific and inconsistent with standards set elsewhere in federal and international chemical control systems and made more impractical with stringent add-up provisions in the AA section. Most concerning is the proposal that there be no default level set at all. Rather DTSC will take "input" from all stakeholders and only be required to consider the limit of chemical detection in setting the threshold level on a case-by-case basis. This is a clear indication that California is not open for business nor for products that are safe for people and the environment.
- Although there are many positive aspects of the proposed Alternative Analysis process, there are a number of critical workability concerns - timelines are too short; the requirements wander away from a strict focus on the Chemical of Concern, serving as the basis for designating a product as priority, with the potential for establishing a regulatory treadmill; and the requirement to account for all direct and indirect cost impacts in the life-cycle of the product.
- A major new concern in Alternative Analysis is the requirement to submit information on a manufacturer's "operating margin", which would unnecessarily require a company to completely open up its books to DTSC. Rather, a straightforward focus on the difference in cost to produce an alternative product is adequate to address the economic feasibility question.
- The regulatory response provisions include no standards for determining the level of response action the Department would take and for what reasons.
- Manufacturers are required to provide a listing of all retail sales outlets – clearly proprietary information that goes beyond DTSC's statutory authority.
- A major new concern in the Trade Secret section is the provision that limits the protection of Chemical Identity related to hazard trait submission. Chemical identity often is the core trade secret for a product and critical to product performance, quality, safety and cost. It should always be claimable as trade secret.
- The regulations would create an enormous paperwork burden for the Department and regulated entities.

California deserves a credible, workable, and successful program that can achieve this part of the Green Chemistry Initiative's objectives, to complement the other five planks of the Initiative. GMA strongly supports many of the improvements in the proposed regulations but still has many important concerns. There is much work remaining for the regulations to achieve the balance of being practical, meaningful and legally defensible. GMA is a member of the Green Chemistry Alliance (GCA) and supports the Alliance's forthcoming detailed comments. In addition, GMA is a member of the Food Packaging Coalition (FPC) and supports the Coalition's comments.

The Grocery Manufacturers Association remains committed to assisting the Department in developing and implementing a Green Chemistry program that will not only achieve the Green Chemistry Initiative's objectives, but that will also be a model for the U.S. and elsewhere. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,



John Hewitt
Director, State Affairs
Grocery Manufacturers Association
1215 K Street, Suite 1700
Sacramento, CA 95814
916-508-6278

cc The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA
Kristin Stauffacher, Assistant Secretary, CalEPA
Debbie Raphael, Director, DTSC
Odette Madriago, Chief Deputy Director, DTSC
Jeff Wong, Deputy Director Science, Pollution Prevention & Technology, DTSC
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor

Detailed Comments

Overarching Issues

Regulatory Duplication. The applicability of the proposed regulation is overly broad. As written, these regulations enable the Department to regulate almost any product for any use. At best, this is potentially redundant with medical device, food and drug, and occupational health and safety rules, but could possibly create conflicts with devices or products that are regulated under other authorities.

Under the proposed regulation, regulatory duplication provisions of the statute are not considered until the product prioritization section and again at the regulatory response section of the regulation. Further, it gives the Department the discretion to determine the adequacy of the regulatory requirements currently in place as they compare to the breadth of the Safer Consumer Products regulation's review. This discretion was not intended by the Legislature, authorized by the statute under SB 509 (Simitian, 2008), nor is it necessary. Rather, it is an example of regulatory overreach, suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. This is not a question of the breadth or sufficiency of current regulatory authority and its implementation. Again, the statute under SB 509 (Simitian, 2008; Health & Safety Code §25257.1(b) and (c)) is clear on the matter, with two applicable provisions:

(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.

(c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

The proposed regulation goes beyond the statute to assert Department dominance where it believes it would provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were not listed as a Priority Product. It is essential that any applicability of the Safer Consumer Products regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently reviewed. In this regard, regulatory duplication for any product should be an upfront and straightforward question in the applicability stage of the regulation – is the potential health or environmental impact from the chemical in the product regulated by another regulatory agency or not? Completing the listing, prioritization, analysis and regulatory response of a product and/or chemical that is already regulated is a waste of limited DTSC resources and fails to meet the practical standard the Department and Director are seeking. Further, where that is the case, by definition any action by the Department would be regulatory duplication, which is prohibited by the statute.

Science-based Processes. To build confidence in the Green Chemistry Program, DTSC must operate the program with a rigorous, science-based approach, in concert with state, federal and international best practices. This must be implemented in the selection chemicals of concern and priority products, in identifying an AA Threshold, in the AA process and in determining regulatory responses. The proposed regulations raise significant concerns that the Department does not intend to do so, but rather intends to structure a system that could pander to the latest sensationalist junk science story. The concerns start with the use of the narrative standard, which is ultimately subjective and facilitates a political, not scientific, basis for

prioritization. The concerns are furthered by inadequate definitions for “reliable information” and “reliable information demonstrating the occurrence of exposure”, which do not require a means to assess the quality of information, but rather the fact that someone has just put it into the public domain. This is further exacerbated with an absence of emphasis on a weight of evidence evaluation of information, but rather the dependence on the “most protective” study independent of its actual quality and reliability. And it’s taken to an even more unscientific position by indicating that when other factors are equal, decisions will not necessarily be driven by conclusions from the most relevant and highest quality studies, but rather from the “greater amount of information”.

In evaluating information to make decisions and substantiate their conclusions about “the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts”, DTSC should be guided by the following principles:

- DTSC’s decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for stakeholders to have sufficient confidence in their use for health and environmental regulatory decision-making.
- All evaluations – by DTSC in determining chemicals of concern, priority products, AA thresholds and regulatory responses and by responsible entities in conducting alternative analyses – must rely on the best available scientific information regarding possible hazards and risks of substances, and employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure.
- Transparent criteria must be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.
- All evaluations must be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.
- Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks. The characterization should provide a full picture of what is known and what has been inferred, and should also present results based on alternative plausible assumptions.
- Assessments must provide full disclosure of key information. When assumptions (or policy preferences) are used in lieu of scientific data, the assumptions (and policy preferences) must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

DTSC should incorporate these principles into Article 1 of the regulations to provide the overall theme and foundation for science-based implementation.

Interstate Commerce. GMA strongly objects to the proposed regulations because they would impose significant burdens on businesses that import their products into California, which vastly outweigh any purported legitimate benefit. The Regulations impose burdens on the import of goods into California by requiring a detailed analysis not only of the contents of the products, but also the manner in which these products were produced and transported to

California. DTSC acknowledges that “[r]esponsible entities will bear real costs as a result of these regulations,” but that “[s]ince most product manufacturing takes place outside California,” the expected “direct short-run California employment impacts [would] be minimal.”¹ Indeed, DTSC has adopted the view that “California firms have an edge in gaining . . . market share” for developing “greener alternatives” under the Regulations. *Id.* at 5. According to DTSC, the Regulations establish “new ‘rules of the game’” governing the import of products in California. Under these “new rules,” “California’s firms are likely to [be] among the most nimble in responding and thriving in the new regulatory environment.” *Id.* at 9. California lacks authority to set the “rules of the game” governing the interstate and international market for consumer goods sold in California in a manner designed to benefit California economic interests.

The Regulations should not be adopted because they impose substantial barriers to the California market by allowing DTSC to co-opt the decisions of California consumers and authorize DTSC to dictate whether or not products – including safe products – can be marketed in California based on, for example, the manner in which they are manufactured outside California. *See Economic Analysis*, at 9 (acknowledging that some products “are likely to be banned”). The Regulations authorize DTSC to deny California residents the opportunity to decide whether to purchase a product based on DTSC’s assessment of the manner in which the product was produced or whether another means of production would render a competing product economically feasible. These Regulations impose significant costs on manufacturers that must bear the burden of testing their products, conducting alternative analyses, and then complying with the regulatory response dictated by DTSC. These barriers especially harm small businesses that lack the resources to comply with these burdensome regulations.

In contrast, there are limited, if any, benefits from the Regulations. Chemical ingredients in consumer products already are subject to regulation at the national level by the Toxic Chemical and Substances Act administered by US EPA and the Federal Hazardous Substances Act as well as other statutes administered by the Consumer Product Safety Commission. Likewise, federal law prohibits the marketing of adulterated cosmetics – i.e., cosmetics that contain any poisonous or deleterious substance that may render them injurious – under the Federal Food, Drug and Cosmetics Act. 21 U.S.C. § 361. In addition to these national, uniform standards, manufacturers already have strong incentives to ensure that their products are safe and effective both by market mechanisms through which consumers, presented with a choice, will purchase products with safer ingredients as well as remedies to consumers injured by products that are actually unsafe. The proposed regulation seeks to replace these existing protections and informed consumer choice with local government mandates. Indeed, DTSC has made no effort to demonstrate that the burdens imposed by the Regulations remotely justify the substantial costs that DTSC acknowledges that would be imposed on importers of products into the California market

CEQA Exemption The notice for the proposed regulations states that DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.) and that DTSC has prepared a Notice of Exemption from the California Environmental Quality Act. While it might be difficult to precisely quantify all of the potential impacts of the Safer Consumer Products regulations at this time, that does not justify a

¹ Matthew E. Kahn, *Economic Analysis of California’s Green Chemistry Regulations for Safer Consumer Products*, at 4, 5 (Mar. 2012) (“*Economic Analysis*”).

complete exemption of such an analysis. We believe that a CEQA analysis is fundamental to best regulatory practices and DTSC should initiate one as part of this rulemaking.

Economic and Fiscal Impact Statement and Economic Analysis. The statement as filed by the DTSC for the Safer Consumer Products Regulation is inadequate and devoid of any substantive information. The recurring theme throughout the document is that the economic and fiscal impact of the proposed regulation will only be quantifiable after the regulation is implemented and operating. Given that the DTSC has afforded the proposed regulation “landmark” status, the inadequacy of the document is even more glaring. The DTSC appears to have failed to even attempt to provide any meaningful data, choosing instead to rely on a previous work, *“Economic Analysis for California’s Green Chemistry Regulations for Safer Consumer Products”* prepared by Matthew E. Kahn for the economic analysis. A careful review of this document reveals that the analysis is based on a biased and largely unsubstantiated perspective.

The entire tone of the economic analysis negatively portrays industry with unsubstantiated generalizations that characterize industry as “profit seeking” with “agendas” that do not align with the spirit and intent of the regulations. Much of the economic and social benefits that are purported to arise from the implementation of the Proposed Regulations are based on the supposition that industry does not currently take responsibility for the composition and safety of its products. It is based on numerous fallacies, for instance:

- that it is not incumbent upon manufacturers to produce products that are safe for their intended use and in compliance with regulations;
- that manufacturers know little about the composition and safety of their products;
- that there will be economic benefit to the State of California and consumers if industry is forced to better understand the composition of their products;
- that the loss of trade secrets under the regulation will be a low probability event;
- that higher short run costs are justified by lower long run costs;
- that any societal benefits will be realized or any corresponding economic benefits from this program;
- that there is any parallel between the proposed regulation and REACH.

Given the importance of this regulation and its potential for impacts on California consumers and businesses, the Department should conduct a rigorous, meaningful and accurate Economic and Fiscal Analyses.

Specific Issues

§69501.2 Definitions

Definitions for “**adverse impacts**”, “**reliable information**” and “**reliable information demonstrating the occurrence of exposures**” although modified, remain scientifically inadequate. They focus on the existence of a hazard or exposure only. No thresholds are included to account for potency and likelihood of harm in making decisions and implementing the regulations.

Chemical ingredient – A chemical ingredient is one that serves a function in the final product. However, as currently written in the proposed regulations, chemical ingredient overlaps with the definition of chemical. Additionally, contaminants could be considered as a “chemical ingredient”. The following revision is suggested:

“Chemical ingredient” means a chemical **that serves an intended function** in a consumer product.

Functionally acceptable - The regulation proposes a change from the earlier draft definition, which was that the alternative “substantially equals or exceeds the performance and functionality of the original product”. The proposed definition is a much lower standard “the product performs the functions of the original product sufficiently well that consumer can reasonably be anticipated to accept the product in the marketplace.” The earlier definition is more directly and quickly measurable. The new definition will add many months to the AA timeline, to enable sufficient consumer testing to draw a conclusion.

Homogeneous Material - In this version of the regs, the distinction of ‘assembled product’ has been eliminated and a new term identified - "homogeneous material".

(34) “Homogeneous material” means either of the following:

(A) One material of uniform composition throughout; or

(B) A material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, or abrasive processes.

It comes into play as potentially being the focus of an AA by being defined as a "product" which means, among other things

"A component, or a homogeneous material within a component, that is identified, under section 69503.4(a)(2)(B), as the minimum required focus of an AA."

While six substances are restricted at the homogenous material level in electronic products in “ROHS” rules in Europe, this concept is appropriate for the scope of chemicals and products that will be covered in the California regulation. There would be great difficulty and uncertainty in defining it and in the case of polymers there would be an infinite number of variations. Beyond the impracticality, it’s not clear why this is needed – ‘component’ should satisfy all needs for the focus of an AA. And given the definition concerning the inability to separate it into different materials, it’s hard to see how this could be a safety concern. For the following reasons, GMA believes that this term be removed and that the regulation focus on “component” in addressing assembled article types of products.

- Very difficult to enforce compared to a focus on the component level. A company cannot easily test to this definition, creating ambiguity for both the agency and industry
- This is a specific regulatory term for a single sector (electronic industry) – not broadly applicable nor scalable to other consumer product sectors
- It applies currently to only a small number of regulated substances (limited to six substances) in one industry sector – not readily scalable to additional substances and very difficult to obtain information/data which can delay implementation of program
- Information on assembled products is being collected in supply chains at the level of component / article for substances of very high concern under REACH. With the homogeneous materials concept, this data would not be applicable, resulting in longer implementation timelines and significant additional administrative burden for agency/industry with minimal environmental benefit.

Legal requirements - Regulations in other states or countries are not acknowledged in the proposed regulation. For instance, many products are made for the North American or even global market. The following revision is suggested:

“Legal requirements” means specifications and/or performance standards that a chemical or a product or product packaging is required to meet by federal or California **or other state or international** law.

Reliable Information – While there are some helpful improvements to this definition, the fundamental problem has not been addressed or resolved. The revised definition identifies a wide variety of sources of scientific information and makes a *de facto* determination that they are “reliable”. All of the sources mentioned are certainly appropriate for consideration in making decisions. Some include deliberative scientific processes that actually review the information in studies and judge weight-of-evidence and other factors, e.g. National Academies and reports from government agencies. In such cases, they may be considered reliable. However, defining everything from every other sources as *de facto* “reliable” is scientifically bankrupt and has the potential to drive controversy into a program that is intended to be science-based. In particular, (A) “Published in a scientifically peer reviewed report or other literature” is problematic. First, “other literature” is open-ended and could include all manner of unreliable information. Second, it is well established that individual published peer-reviewed studies can be unreliable.

This problem is carried through to definition (53) “Reliable information demonstrating the occurrence or potential occurrence of exposures to a chemicals”, which includes a variety of sources of exposure information, but again includes a *de facto* determination of the sources as reliable, independent of the actual reliability of any specific studies.

What would DTSC do in a case where there are four peer-reviewed studies that provide entirely different results, or four studies from a variety of the listed sources that come to different conclusions? By the Department’s current definition they are all “reliable information”. GMA believes they should not automatically be considered as such.

The need for a mechanism to judge studies for relevance and reliability is widely recognized by federal agencies with health and safety responsibility and in international fora. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology has been used for determining data quality and reliability on tens of thousands of studies for over 2000 chemicals in US and OECD HPV programs. Hundreds of thousands of studies on over 5000 chemicals have been submitted to REACH and were rated according to this approach. The same is to occur for additional thousands of chemicals in future years. The methodology is published as Chapter 3 in the OECD’s Manual for Investigation of HPV studies.

http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

GMA reiterates our recommendation that the department provide separate definitions for “Information Sources” to include the diverse sources listed in (52) and (53) and then to determine reliability by subjecting those studies to this definition for “Reliable Information” based on the OECD Manual:

“Reliable information” is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing

guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship ("QSAR") approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies.

http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html

GMA supports one aspect of the definition of reliable information demonstrating exposure – (53)(D) 1, describing exposure or modeled point concentrations associated with adverse public health impacts. This comparison of hazard and exposure information to indicate the potential of harm makes great scientific sense and should be similar language should be added to (A), (B), and (C) in this definition.

Safer alternative – Recommend a change in the definition: “Safer alternative” means an alternative that, in comparison with the existing Priority Product, ~~reduces, avoids, or eliminates the use of, and/or potential exposures to, one or more Chemical(s) of Concern, so as is~~ **determined by the Alternatives Analysis** to reduce adverse public health and environmental impacts.

Adverse Impact – Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, and waste/end-of-life related to hazard traits. Many traits are traditional endpoints addressed in state, federal and international chemical programs. However, there are several critical concerns in these definitions.

Scientific Frontier –The first is that some factors are scientific frontier issues—for instance epigenetic toxicity—that are not settled science and lack widely accepted evaluation methodologies, but are included in OEHHA’s hazard traits and by reference in these regulations. We have argued that such traits do not belong in these regulations and should be removed. Peer reviewers suggest that “epigenetics” is a valid endpoint as long as it is toxicity-related. However, this makes the implicit assumption that we know which “epigenetic” changes are implicated in the etiology of disease and that is not yet the case. Since epigenetics is an unproven and ambiguous area of toxicology, GMA believes it should be removed from the definition of an adverse health impact at this time.

Thresholds –An overriding concern with the adverse impact and chemical property definitions is that there are no threshold levels to provide a context for what is of concern. All chemicals, including water, have toxic impacts across a variety of hazard traits at some measurable level. The absence of thresholds in the regulations suggests that every substance could be considered a Chemical of Concern or be included for the purposes of AA Threshold determination, Alternative Analysis and Regulatory Response because it has some impact, no matter how small or large, regardless of potency. Thresholds are a part of chemical control systems worldwide as a means to help identify priorities, particularly in the PBT and chronic toxicity arena. The definitions should include thresholds and clearly convey the potential for adverse impacts in the context of thresholds.

Bioaccumulation – GMA has previously noted that the proposed definition for bioaccumulation was inconsistent with nationally and internationally accepted definitions, which specifically include thresholds. Peer reviewers have also commented on this issue. In this iteration, there is further confusion in that there are two definitions, the previous DTSC definition AND a reference to OEHHA’s hazard traits. It’s not clear why such an important chemical property, with a long history of federal and international standard setting and chemical control actions, should be defined with a unique to California approach. This will disconnect the state from the capability to use any existing data and scientific approaches, slowing Green Chemistry progress as the Department attempts to translate all of the extensive information, learnings and actions from global programs into a California-unique approach. This is particularly troubling given the fact that no threshold is identified for a property that in testing yields a measured, non-zero value. GMA reiterates the recommendation that the bioaccumulation definition be changed to be consistent with definitions in the following:

EPA policy statement entitled ‘Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances’ (64 Fed. Reg. 60194; Nov. 4, 1999).

Stockholm Convention on Persistent Organic Pollutants
<http://chm.pops.int/default.aspx>

§69502 Chemicals of Concern Identification Process

The Proposed Regulation starts with a consolidated list of chemicals from 22 source lists at the effective date of the Regulation, resulting from the merging of all the items on the lists. In fact, these lists contain well over 4,000 distinct chemicals. DTSC has indicated that the list it will publish will contain 1200 chemicals, but does not indicate how the reduction will take place other than indicating that it will take out the approximately 450 pesticides and pharmaceuticals that are exempted from the regulation. Of course CAS numbers must be used to identify each chemical on the list.² Contrary to the overall direction for developing these regulations, the approach is not Practical, not Meaningful and not Legally Defensible. There are several major concerns with this approach:

- The statute requires that DTSC establish a process to prioritize chemicals of concern. The proposed approach does no prioritization whatsoever, and thus is not legally defensible.
- Lists are developed for varied purposes. Merging them with no prioritization for the Department’s specific purpose results in the identification of items that are not meaningful and have no place in a chemical of concern list—oxygen, nitrogen, iron, aluminum, silver, exotic species, contraceptives, marijuana smoke, viruses, salted fish, wood dust, sediment, and others. Each of these items is relevant to the purpose of the contributing list, but irrelevant to the SCP regulation.
- While listing 4000 or 1200 chemicals may give the appearance of providing expansive public protection, in fact it creates a meaningless, untargeted and low-resolution

² It must be noted that this regulation, like every other chemical regulation must specify unique Chemical Abstract Services numbers (CAS RN) and cannot utilize generic chemical categories. For instance, the perfluoro chemical category contains many hundreds of different unique CAS RN chemicals, each with its own properties. Good compliance and the ability to enforce the regulations requires the clarity of a unique CAS RN associated with chemical of concern lists, priority product determination, AA threshold concentrations, the conduct of AA’s and regulatory responses.

concoction. Nearly 50% of the over 4000 substances are not even on the TSCA inventory making them illegal in US commerce³; More than 80% were not reported as manufactured or imported into the US in EPA's most recent update; and 90% are not used in consumer products.

- The identification of all, or a portion of chemicals on the 22 lists does not meet the statutory mandate to consider hazard and exposure, nor even the Department's criteria for adding new chemicals to the list, which requires an analysis of available reliable information on both hazard (adverse impacts) and exposure.
- The establishment of a non-credible list of 4,000 or even 1200 substances will become irrelevant and do little to motivate broad-based action by manufacturers. It is so overwhelming that it will have the opposite effect—more likely, all except those involved in selected Priority Product/Chemical of Concern pairs will ignore it. The massive haystack created here hides the important needles that should be the real focus of this program.
- As GMA has advocated for the past 4 years, it makes sense to call this larger list “Chemicals of Interest” or similar, but for DTSC to go further to establish a narrowed list of “Chemicals of Concern”.
- Numerous jurisdictions have done just that, identifying longer lists of chemicals with no direct regulatory implications and that may be considered in the future and then going on to identify much shorter focused lists that do have direct regulatory implications and that are the focus for current action. DTSC has identified many of these in an exhibit circulated with the regulations “COC Lists Around the Globe”, noting “Broad Lists” and “Current Focused Lists” in a number of jurisdictions. However the exhibit does not appropriately characterize the “Broad Lists”, which in nearly every case have no regulatory implications. The proposed SCP CoC Broad List would have direct regulatory implications.

Prioritizing Chemicals of Concern. Actual prioritization of chemicals of concern considering both hazard and indicators of exposure gives credibility to the process. In the long term it will conserve Department and regulated community resources; and the statute mandates it. As noted in the GMA cover letter, the proposed regulations describe an approach that the Department indicates will identify approximately 185 Chemicals of Concern for the initial focus in the program through 2016. GMA strongly supports the concept behind this approach, which uses information on chemical hazard together with indicators of exposure to narrow the field. This is a critically important step forward, highlighting a core group of substances to make progress on in the initial years of the program, while sending an important signal to the marketplace on a more tightly focused list. However, it should not be a one time arrangement, rather there should be a periodic process to identify a narrowed list on the basis of hazard and indicators of exposure.

GMA continues to recommend the following alternative approach to prioritize chemicals of concern to a narrowed and focused list. This can be completed in a timely way—within 90 days of the publication of the regulation—and not slow progress in implementing the regulations. The Department should:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes

³ Not all chemicals have to be included on the TSCA inventory: chemicals which are used in pesticides and in FDA-regulated products do not have to be registered under TSCA, however most are.

with the opportunity for stakeholder input and comment (specific recommendations below);

- Merge those lists to generate a set of “chemicals of interest”;
- Conduct an actual prioritization/screening to identify real Chemicals of Concern.

This would encompass several steps:

1. Clean up the merged lists—remove pesticides, pharmaceuticals, and other substances that are not chemical compounds to which the regulations apply.
2. Narrow the result from above to identify chemicals made or imported into the U.S. using EPA, FDA and other exposure information such as biomonitoring data;
3. Further narrow the result to chemicals used in consumer products in the U.S. using EPA, FDA and other information;
4. Publish the proposed Chemical of Concern list for comment.
5. Finalize the list.

This approach has several benefits: it can be done quickly without diverting DTSC’s other efforts to implement the regulation; it produces a large list of “chemicals of interest” that can serve as a broader marketplace signal, any one of which can readily be moved to a chemical of concern if it is placed into consumer products; it produces a narrowed and targeted list of chemicals of concern not just to support DTSC’s further work, but that will be more likely to prompt action in the marketplace beyond just DTSC’s selected Chemicals of Concern/Priority Products; it will more likely have influence in other states and at the federal level, in contrast to the existing proposed approach naming thousands of chemicals, which will have no impact. It can be updated periodically based on new information on both hazard and exposure.

Concerns on Source Lists. As noted above, a variety of source lists are appropriate and will be useful as a starting point in a true prioritization process. GMA appreciates DTSC efforts to modify the previous draft of source lists to better represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment. There are several remaining concerns.:

- (1)(C) is the European Union’s endocrine disruptor list. This should be dropped as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input. The list was discredited by the EU’s scientific advisors. The objective in creating the list was to identify chemicals that deserved further investigation on whether they are endocrine disruptors, but that was never done and there has been no EU regulatory attention to the list for 5 years.
- (1)(H) is Canada’s prioritization list of potential PBT compounds, mostly based on modeling and completed in 2007. Since that time Environment Canada has conducted hundreds of assessments in its Chemical Management Program leading to determinations in a number of cases that a chemical is not in fact PBT. The Department should adopt its Chemical of Interest and Chemical of Concern lists utilizing the most up-to-date information.
- (1)(I) is IARC’s Carcinogen list. GMA strongly disagrees with inclusion of 2B substances, as the evidence level is less than that of other international Carcinogen sources.
- (1)(L) is the Office of Health Assessment and Translation reproductive and developmental toxicants. GMA agrees with this source, but notes that chemicals

included in the Green Chemistry program should be those identified as Serious Concern and Concern.

- (2)(F) is the California Biomonitoring program, where numerous chemicals have been listed, some of which are beyond those tested in the CDC Biomonitoring program. The California program is in the early stages, and little testing has been completed and validated. None of the chemicals that are beyond CDC's studies and which have not yet been studied in California's program should be considered to have "exposure information" under this regulation.
- (2)(H) is the OSPAR list of substances for priority action. This should be dropped as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input.

Adding Entire Chemical Lists. Article 4 allows Petitioners to request the addition of entire lists of chemicals. GMA opposes this approach. New chemicals of concern should be individually petitioned and considered on a case by case basis, considering available and reliable information on hazard and indicators of exposure.

§69503 Product prioritization

GMA supported AB 1879 and SB 509 as a means to place decisions about product safety in the hands of DTSC scientists. In previous comments, we have supported and recommended a prioritization process that would require the Department to make quantitative comparisons of hazard and exposure in setting priorities and to focus on those situations with the greatest potential for harm. DTSC must employ a rigorous scientific process for selecting chemical of concern/priority product pairs. GMA prepared an in-depth report and suggestions on a quantitative process that would ensure such an outcome and that has already been successfully employed internationally. This is posted on DTSC's website under the headline "Chemical/Product Prioritization Resources"

<http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/index.cfm>

Unfortunately, these ideas do not seem to be employed in the Proposed Regulations. Instead, a "Narrative Standard" is envisioned. The process outlined has three aspects.

- (a) Consideration of a wide set of potential adverse impacts and exposures, the availability of information, and the protections addressed and afforded by other regulatory programs.
- (b) Consideration of Key Prioritization Criteria
- (c) A description of a process for moving through selection that evaluates products based on the factors in (a) to identify high priority products. That evaluation can be adjusted based on the ready availability of a safer alternative and the scope of other product regulatory programs. Finally, the list is reviewed for consistency with (b).

GMA appreciates a number of changes from the previous draft and strongly encourages the Department to include them in the final regulations.

- The process considers both hazard and exposure in setting priorities.
- The term "potential" has been largely dropped (e.g. potential adverse effects, potential exposures, etc.) better focusing on real health and environmental concerns.
- The inclusion of "extent" and "level" in (a)(1)(B)4.c. which describes the approach for quantifying exposure in use and end of life scenarios.
- The tightening of Key Prioritization Factors and requiring that Priority Product/CoC pairs must meet both criteria.

- The elimination of unnecessary distinctions between assembled and formulated products.
- The concept of a Priority Product Workplan outlining the Department's direction for 3 year periods.

Nevertheless, the Proposed product prioritization process continues to be problematic in a number of ways.

- The factors in (a) are very broad-based and important. However, the focus in the exposure criteria often seems to be on 'presence', 'contact' and 'occurrence', which are not the same as exposure. This suggests an entirely qualitative evaluation, which could result in opinions and emotion driving the process, potentially resulting in arbitrary decisions rather than a deliberative scientific effort to identify high priorities—i.e., real and significant threats to public health and the environment. Qualitative information, while directionally helpful in indicating the existence of occurrence, contact or presence, cannot be used in determining whether a situation presents an exposure with the potential for adverse impacts. Presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern must be a primary driving factor in priority setting decisions. The one provision that mitigates this concern is the Key Prioritization factor: "There is significant ability for public and/or aquatic, avian or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts". This is similar to the language in previous iterations of the proposed regulations, and GMA strongly supports maintaining this provision in the Regulation.
- GMA supports the Department's approach to identify Key Prioritization Criteria in (b) of this article; however, the criteria are employed as an afterthought in the process, and only "reviewed for consistency" in (c). Instead they should be applied as the critical prioritization process step after evaluations in (a) have occurred to determine whether a product/chemical combination is a high priority. If they are not used for the critical prioritization step, then product prioritization becomes an entirely arbitrary process.
- The Proposed regulations have abandoned any focus on intentional ingredients, those chemicals purposefully included in a product to perform a function. GMA has maintained that the program will be most successful with such a focus. A focus on chasing unintentional trace levels will significantly diminish the public health and environmental benefits of the program. DTSC seems to make its intent clear in presentations, identifying example priority products with chemicals of concern that are intentionally added to perform a function in the final product. Products that contain CoC should not be designated as Priority Products if such CoC are present because of typical low-level impurities in raw materials that are not a concern for safety and while controlled, are not economically feasible to remove. To ensure that prioritization is focused on substituting chemistries that are most likely to have the greatest potential risk to the public, GMA recommends that DTSC consider only chemicals that have been intentionally added, have a function in the product and are above the AA threshold level when making product prioritization decisions.

In selecting and identifying Priority Products, the Department should use a standardized product nomenclature system. The ISOR makes reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing Section 69503.3(f). GMA agrees that the GS1 GPC is the appropriate source for describing products and that Priority Products should

be identified at the Brick Level. Priority Product categories should be described at the Class Level for the purposes of the Department's Priority Product Work Plan.

§69501.2, 69503 and 69505 AA Threshold Concentration

GMA has consistently advocated for the inclusion of a *de minimis* threshold in the Proposed Regulation with a default level of 0.1%. With ever improving analytical capability and ever-lower detection limits, vanishingly small and insignificant levels can be identified. These are great for generating headlines, but meaningless in protecting public health. Threshold provisions are standard in a variety of chemical and product safety laws. Europe's REACH chemical law applies a 0.1% *de minimis* level as a default in products. REACH's 0.1% *de minimis* applies broadly, even to so-called Substances of Very High Concern that become banned in Europe. The European cosmetic directive also includes a 0.1% *de minimis* level for over 1300 carcinogens and reproductive toxicants. This same level is also used in worker and transportation regulations in Europe and North America. GMA believes that California should be consistent with other national and international laws. The basis for these laws is that low, but measurable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low.

In addition, GMA has supported the concept that DTSC should be able to adjust the threshold from the default based on sound science and reliable information. Experience in the European Classification system (EC No. 1272/2008) is that for 85% of the over 4000 chemicals with classified hazards, the threshold is 0.1%; for the remaining 15% the EU has determined a different level—sometimes lower and sometimes higher. This covers all hazard traits, including those that are applicable in DTSC's most stringent provision.

The Proposed Regulation eliminates the adoption of a default threshold and replaces it with a case-by-case threshold. GMA adamantly disagrees with this direction and requests that the Department reconsider establishing the threshold in the final regulations at 0.1% for all hazard traits, consistent with established national and international approaches. In addition, GMA does not support the concept that the threshold should be based on adding the concentrations of multiple Chemicals of Concern with similar hazard traits. No other threshold systems in the world employ this approach. This suggested approach would add an additional order of magnitude of conservatism, rendering it significantly more precautionary.

Some stakeholders have suggested that "0" is an appropriate threshold. "0" is impractical, is a technically impossible regulatory standard to measure and comply with, and provides no additional benefit to public health and the environment.

A specific suggestion, if the Department continues in the proposed approach is to add to (c)(1)(D) "A processing agent, **reactant, by-product or intermediate** frequently used to promote certain chemical or physical changes..."

Exemption Notification. Requiring manufacturers to apply for an exemption is counter to the spirit and intent of the regulations – which acknowledge that minimal concern exists for such extremely small levels of a chemical in a product. Additionally, the process is unnecessarily cumbersome, and requires the release of proprietary data (which may become public) for products that are not a priority and pose no human health or environmental concerns. Further, the capability to develop and validate test methods that will be reliable for a particular formulation, testing with lab QA/QC to produce data on all product variations, summarizing, signing and submitting to DTSC would take much longer than the 60 days allotted. This is

particularly egregious in a situation where a manufacturer is not formulating the product with the CoC and has protocols in place with raw material suppliers to ensure that ingredients are provided as specified. GMA recommends that testing products should not be the default, but rather, a short form for exemption notifications should be put in place, where the manufacturer informs DTSC that they produce the product, and certifies that the CoC is below the AA Threshold. Upon request, DTSC could be provided with the information substantiating the certification. Also this section indicates that notifiers must report the name and contact information for all responsible entities for the product, which seems to indicate a manufacturer must report on every retail outlet where the product is sold. This is unnecessarily burdensome, and goes beyond the authority provided in the statute.

Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2]. As DTSC acknowledges in their “Initial Statement of Reasons” (ISOR) [Section 69503.2], there is little to no exposure to a “Chemical of Concern” (CoC) from inaccessible components. In order to provide appropriate focus to the prioritization process, there is a need to define “inaccessible components” and remove these components from prioritization. This approach is consistent with California’s statute, and similar laws regulating the presence of chemicals in products in Washington State, Maine and on the federal level under the Consumer Product Safety Improvement Act. To address this concern, DTSC should define “inaccessible components” and reference that in several key places in the regulation to prevent the regulations from overreaching and focusing on components where there is no reasonable likelihood of exposure.

§69505 Alternative Analysis

Alternative Analysis (AA) in the Research and Development Paradigm. The alternatives analysis process is essential for developing safe and innovative consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs, expectations, and preferences, is the ability for manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives.

Alternatives analysis may be undertaken by individual chemical manufacturers and/or formulators, or by consortia (with some limitations) representing an industry segment or an entire industry. Due consideration to safety, complexity (different factors are relevant to a specific chemical/product/use combination, and must be evaluated on a case-by-case basis), effectiveness, lifecycle thinking, **consumer acceptance**, cost to consumers, processability or manufacturability, and informed decision-making (weighing trade-offs) will ensure a workable, practical, and meaningful Green Chemistry program in California. The most appropriate alternative for a particular product would be selected by the product manufacturer to ensure that it fits well within their unique business model.

A rational, structured and predictable alternatives analysis process is essential from a business perspective. The Department must not “pick and choose” between AAs and mandate a particular alternative, but rather evaluate AAs to ensure that they meet the statutory requirements. A manufacturer has met their statutory obligation when an adequate AA has

been completed. The Department may propose varying regulatory responses for a designated chemical of concern (CoC)/priority product (PP) pairing.

The product improvement process is iterative, complex, and different on a product-by-product, case-by-case basis. A sensible regulatory approach for conducting an AA should:

- Ensure consumer acceptance – The alternative must provide the same or better performance and *value* to the consumer.
- Be Flexible - Each business model is different: even for similar chemicals/products, the AA outcome may be different (due to, for example, innovative processes or design features or target consumers). Each manufacturer must be given the latitude to leverage existing tools and approaches to evaluate alternative ingredients/components for their products as appropriate.
- Be Modular - Although all criteria are considered in a multi-factorial evaluation matrix, the most critical parameters are identified and further evaluated for each case.
- Be Effective - An AA has to be practical and meaningful (not just paperwork) in which the change provides a significant benefit to public health or the environment.
- Incorporate Informed Decision-making – Trade-offs must be understood and considered to avoid unintended consequences.
- Allow for a gradual and measured implementation of appropriate or suitable alternatives - Adequate time is necessary to introduce a new product into the marketplace due to complex and lengthy design considerations, development of supply chains, ensuring regulatory compliance, and ensuring and verifying consumer acceptance.
- Include a feasibility check - Provide the opportunity for the reanalysis of the regulatory response prior to the deadline for action, should new data or subsequent analysis uncover previously unforeseen concerns with implementing the required regulatory compliance options, similar to the approach California’s Air Resources Board (CARB) employs.
- Ensure that an alternative formulation meets legal requirements, especially when considering patent issues and other state and federal regulations.

Positive Aspects of the Alternatives Analysis Portion of the Draft Regulation. The following highlight the positive aspects of the draft regulations in regards to Alternatives Analysis (AA) that should be kept as a part of the final regulation:

- The scope of the Alternatives Analysis is focused on a specific Priority Product that contains a CoC serving as basis for listing a product as priority. (§ 69503.4(a)(2), § 69505.1. (c)(2))
- Alternatives Analysis is appropriately defined as “[A]n evaluation and comparison of a Priority Product and one or more alternatives to the product, under article 5” (§ 69501.1.(a)(12))
- “Functionally acceptable” appropriately focuses on both product legal requirements and consumer acceptability. However, the alternative product should meet or exceed performance of the original product, not “sufficiently” perform.) (§ 69501.1.(a)(31))
- "Technically and economically feasible alternative" incorporates consumer demand but could benefit from including several other criteria. (§ 69501.1.(a)(59))
- AA is required for only those priority products containing the CoC above the AA threshold (§ 69503.5.) that continue to be placed into the marketplace after the priority product listing.

- Provision eliminating the need for any further evaluation after the first stage of AA if the manufacturer claims that a “functionally acceptable” alternative is not available. Submission of an abridged AA report would be required within 180 days of the product being listed as priority. (§ 69505.2.(b))
- Inclusion of § 69501.2.(a)(2) and § 69505.1. (c)(1), wherein the requirements of this chapter applicable to a responsible entity may be fulfilled either entirely or partially by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity. (Limitations to the use of this section are noted below. However, this does allow for some creative management of substantial portions of an AA to reduce resource costs that may prove especially beneficial to Subject Matter Experts.)
- Inclusion of the potential for an alternate AA process (§69505.2 (c)).
- Flexibility allowing the manufacturer to use most appropriate methodologies, models, tools, and decision-making process to assess the CoC/PP pair alongside potential alternatives, and to make a determination of the selected alternative (within the context of the company’s product position in the marketplace) and the opportunity to propose the most appropriate regulatory response (§ 69505.5 (h), (j), and (k)(2)(B)).
- The allowance for a feasibility assessment after AA report submission, and opportunity to select a different alternative, provided that an updated report outlining the rationale for the change is submitted to the Department (§ 69505.2. (d)(1))
- Only relevant factors need to be considered further, while allowing the manufacturer to explain why other factors are not relevant to the analysis.
- The Two Stage tiered-process envisioned by DTSC is a useful approach. (§ 69505.3. and § 69505.4) The Preliminary AA Report submitted after Stage 1 focuses on the function, performance, and legal requirements of the CoC in the PP and identifies and provides an initial comparison of potential substitutes for relevant impacts. The Final AA Report submitted after Stage 2 focuses on a comparative analysis at the product level integrating all relevant factors.
- Inclusion of § 69505.3.(b)(4), which speaks to the ‘Consideration of Additional Information’, allowing elimination of alternatives for ‘showstopper’ reasons in Stage 1.
- Qualitative as well as quantitative information can be provided for relevant factors. (§ 69505.4.(a)(2) and § 69505.4.(b))
- Providing manufacturers the necessary time to implement their alternative through specifying an Implementation Plan in the final report. (§ 69505.4.(e)(1))
- Including the opportunity within the Implementation Plan to identify any steps necessary to ensure compliance with existing laws.(§ 69505.5.(k)(2)(A))
- Eliminating third-party verification requirements from the draft regulations.
- Lead assessors can be in-house company experts.
- A process to dispute most of the Department’s decisions is described.

Challenges and Opportunities for Improvement

While some of the underlying themes within the proposed draft regulations are appropriate and appear to be consistent with the existing product development paradigm, there remain many challenges and opportunities for improvements to help maintain focus of any required Alternatives Analysis.

I. Timeframes

The timeframe described for preparing Alternatives Analysis reports (i.e., 6- and 12- months for preliminary and final reports, or 60 days and 18 months for AA workplan and final reports) is unreasonable and unworkable should there either be a need to do further experimental research to evaluate a particular alternative or be a desire for a consortium or public-private partnership approach to accomplishing the AA work. There are clear cases where industry-wide efforts have been shown to be the best way to address substitution. Despite the limitations discussed below, there are clear advantages in sharing some tasks and in encouraging economic viability of some otherwise questionable substitutions.

The Responsible Entity will need more than 18 months to identify one or more technically feasible and economically and functionally viable alternatives (even if it is initially a theoretical analysis), develop a safety profile comparison of the base and alternative together with other information on other relevant factors, do adequate market research and gauge consumer acceptance before selecting the most viable alternative, write the submission for the Department and get management approval to submit. Such innovation, when an alternative is not well known can require 3-5 years or more, often with many failed alternatives cast aside at different points in the product development process. For example, for a “simple” substitution in formulated products, a company at a **MINIMUM** would need two months to get scientists & engineers coordinated and in the lab; one year of research to find a material that meets safety and economic requirements, supply, etc. ; three months of process lab testing; six months for testing at the manufacturing plant (to include scheduling for an experiment since plants typically run at capacity); three months of consumer testing (note that not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). From the time one or a few materials are identified for further assessment, on the optimistic side, **AT LEAST** 26 months is necessary for R&D and this is **ONLY IF** an EPA Pre-Manufacturing Notification (PMN) is NOT required. Realistically, a responsible entity should be given 3 years, with the option to extend for another 2 years, plus an additional 1 year if a new chemical PMN is required (as the PMN work may sometimes be done with an R&D exemption).

However, in most cases, substitutions will be much more complex, and the product system may be more complex. Many substitutions will likely require multiple materials to be substituted for the one chemical of concern. A good example is the replacement of phosphate in auto dishwashing (ADW) products. While some companies continue to optimize the formula on phosphate replacement in ADW over the past 25 years, the initial replacement was accomplished in three years. Phosphate replacement required 4 to 5 different chemicals depending on the formulation, in which one of the materials required a PMN (and a New Substance Notification (NSN) in Canada), and another material an NSN.

Stage 2, although indicated by the draft rules as being a theoretical exercise, actually requires lab work to analyze physical alternatives and to help narrow down the list of potential alternatives. Innovation requires resources (i.e., people, finances, and equipment) and time (anywhere from months to years) depending on the size of the project and the complexity of the product. Once the lab research has been completed and the effect of the substitution on the product determined, the material has to be tested in processing labs to see if the new ingredient or series of ingredients can be processed. There are also requirements for compatibility and stability testing. Then, scaling up is necessary at a manufacturing plant. Meanwhile, market research for consumer acceptance is carried out – an iterative process - with relevant and realistic product/material (generated from a manufacturing plant) to ensure that consumer satisfaction is achieved with the final product. Additional special testing for specific claims or

consumer tolerance in use may also extend the timeframe needed. Not only is the proposed timeframe inadequate for research and development, it is clearly inadequate to effectively get a new chemical TSCA-listed under EPA's Pre-Manufacturing Notification (PMN) program.

As mentioned above, there will be situations where a collaborative approach is the best approach to pursue alternatives. Flexibility in timing and report submission is also prudent when the responsible entity is a consortium, trade association, or public-private partnership. Anti-trust requirements in the U.S. demand care in building such relationships, making them cumbersome since communication must involve a third party for oversight and blinding of most communication. It could take 3-4 months to build a consortium, before any analysis is done on a chemical of concern/priority product pairing. And, most likely, the analysis for both Stage 1 and Stage 2 will take more time for a consortium to complete (than for a product manufacturer). Thus, an additional provision should be included in which a consortium is permitted to form within one year of the priority product listing prior to any AA. The oft-repeated experience of the "flame retardants in circuit boards," which is ongoing after more than 6 years, is instructive. Despite a widespread, committed level of interest and effort by the industry in this public-private partnership, there is not yet a fully demonstrated alternative that achieves the goal.

In summary, where an alternative is not readily available, not well known or not already broadly adopted, the 6- and 12-month timings are not workable. These timeframes must be expanded to a minimum of 12 months for a Preliminary Report and 24 months for the final on individual company AA's and 18 months/30 months for consortia. A tiered approach could be utilized considering the simplicity/complexity of the product system and the substitution, the availability of alternatives, the extent of research and development needed to identify and investigate alternatives, and whether a consortium approach is being used. Higher tier approaches could require an upfront workplan and regular reports to provide the department with updates on progress.

II. SCOPE of AA process –Stage 2 and Consortia/Anti-Trust:

IIA. Stage 2 AA:

- (i) **Focus on Designated Chemical of Concern and Alternatives.** A single Chemical of Concern (CoC) should serve as the basis for designating a product as priority and for the Alternative Analysis process.

In the draft regulations as currently written, there is no limitation on the number of CoCs that could serve as the basis for designating a given product as priority. For example, the Department could identify FIVE CoCs as the basis to prioritize a given product. The subsequent AA would require a comparative analysis of all potential alternatives for each CoC in the priority product if collectively their concentrations exceed the AA threshold. The scope and breadth of the analysis would grow exponentially, ultimately leading to paralysis by analysis. To ensure a workable, pragmatic, and meaningful program, the analysis should focus only on ONE CoC in the Priority Product. To avoid "scope creep", the focus of any analysis should be restricted to the single CoC that is the reason for the designation of the priority product.

- (ii) **Relevant Factors.** As mentioned previously, the AA should identify "relevant" factors, which are critical to achieving a focused and efficient AA process. The issue of relevance

is confusing and somewhat arbitrary in § 69505.4 (a)(1). The use of the word “demonstrable” inappropriately implies that even the slightest impact or change would be relevant. What would constitute a “demonstrable contribution” to one or more adverse impact AND a “demonstrable difference” between alternatives?

The point of this exercise is to focus on relevant factors and set aside irrelevant ones, which will have limited to no significant and meaningful impact on the outcome. Thus, the recommendation is that, in the same spirit of AB 1879 with the goal of significantly reducing adverse impacts, “demonstrable” should be replaced with “**significant**”. Significant is an appropriate term and is used as a standard in numerous other places in the draft regulation including the Priority Product/CoC prioritization process, AA Threshold Exemption notification requirements, the Regulatory Response section, and the Accreditation Body section.

The following revision should be made to the draft regulation:

§ 69505.4. (a)(1)(A) A factor... in conjunction with an associated exposure pathway and life cycle segment, is relevant if it would constitute both:

1. It makes a ~~demonstrable~~ **significant** contribution to one or more adverse public health, environmental, waste and end-of-life, and/or materials and resource consumption impacts of the Priority Product and/or one or more alternatives under consideration; and
2. There is a ~~demonstrable~~ **significant** difference in the factor’s contribution to such impact(s) between two or more of the alternatives being considered

Additionally, consumer acceptance is ALWAYS relevant and important. Although a manufacturer has the opportunity to consider consumer acceptance in the alternate AA process, this factor should be explicit among the factors listed in **§ 69505.4. (a)(2)**.

GCA recommends the following language be included in the regulations:

(NEW) § 69505.4. (a)(2)(B)4. A determination of whether there is Consumer Acceptance of the alternative.

- (iii) **Focus on Designated Chemical of Concern and Alternatives.** The scope of the alternatives analysis is broadened substantially when multimedia life cycle impact and chemical hazard considerations are being requested not only for the CoC and its potential substitutes but also for ALL chemical ingredients known to be in the Priority Product and the alternatives. (§ 69505.4.(a)(2)(A)) The focus of any alternatives analysis should be limited to the CoC’s that were the reason for the product’s listing.

If the AA takes on this greatly expanded focus it would seem that manufacturers would have to analyze for all chemicals they use in their products for all factors. This would result in a completely unnecessary waste of resources, moving away from a focused analysis on the most relevant parameters of the alternatives to the CoC. Expanding the focus to a comprehensive analysis of all chemicals found in the product would divert resources from the real purpose of the AA, significantly extend the time necessary for AA completion, and put the green chemistry program in jeopardy of never achieving its objectives of significantly reducing adverse impact to health and the environment.

To ensure that such unauthorized “scope creep” does not occur, it is important to maintain focus of the Alternatives Analysis on the CoC/PP pair and their potential alternatives and to evaluate only substantial changes to the alternative formulation in which other CoC may have been newly added. It is unnecessary, burdensome, and inefficient to require reporting on all chemical ingredients within the product (and/or alternative), thus detracting from the goal of the statute of identifying, prioritizing, and evaluating prioritized CoC that may significantly adversely impact public health/environment.

The recommended language should be revised to:

§ 69505.4. (a)(2)(A) Multimedia life cycle impacts and chemical hazards for chemical(s) of **concern ingredients** known to be in the Priority Product and the alternatives being considered based on available information...

(iv) **Technically and economically feasible alternative.** On the determination of the “technically and economically feasible alternative” (§ 69501.1.(a)(59)), the current definition is:

"Technically and economically feasible alternative" means an alternative product or chemical for which:

- (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and
- (B) The manufacturer’s operating margin is not significantly reduced.

Manufacturer’s operating margin is not a good choice as a criterion for this definition. Operating margin goes well beyond the capital and operating costs to make a product and includes such factors as delivery cost, advertising costs, research and other overhead costs, etc. This economic feasibility should be focused on the impact of the alternative on the cost to produce a product.

The draft regulations should additionally allow the responsible entity to also consider the *availability* of the “functionally acceptable” alternative, *affordability*, and the cost to produce the product.

The recommended language in § 69501.1.(a)(59) should be revised to:

§ 69501.1.(a)(59) "Technically and economically feasible alternative" means an alternative product or chemical for which:

- (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and
- (B) The manufacturer’s operating margin is not significantly reduced **based on the following:**

- 1. The extent to which a functionally acceptable alternative is currently available in the marketplace;**
- 2. The affordability of any currently available functionally acceptable alternative; and ~~and~~**

3. The cost differential to produce a product, including not only the actual material cost difference but also any difference in the processing/manufacturing conditions, between the Priority Product and the alternative.

(v) **Economic Impacts.** [Trade Organization] is pleased the Department is not proposing a default examination of projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered. However, if a responsible entity compares the economic impacts of potential alternatives and the PP and chooses to retain the PP, the responsible entity will be faced with difficult challenges to evaluate both direct and indirect cost impacts. Regarding economic impacts (§ 69505.4.(a)(2)(C)), accounting for all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered to include among others costs to government agency, public, waste and end-of-life management costs is so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Moreover, traditionally, it is the responsibility of the government and not the manufacture to assess the regulatory and macro/micro economic impact of chemical and product alternative regulations as it is government and not industry that is responsible for making public policy decisions. More clear and concrete criteria need to be established by which the regulated entity understands what is required to satisfy this provision. As of today, there are no well-established methodologies that are able to properly assess these types of costs to enable rigorous and meaningful comparisons across all of the A-M elements. The methods are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well-being of Californians or their environment.

(vi) **§ 69505.4(b) Comparison of the Priority Product and Alternatives.**

All of the product development thought process is required to be disclosed, e.g., metrics used to evaluate alternatives, weights applied to the various factors, and ultimate selection of an alternative. These decisions are value judgments, are the fundamental underpinnings of business innovation and are different company to company. The Department must ensure that this sensitive trade secret information is protected. However, assurances are lacking in the current draft rule since § 69505.5(a)(6) states, “The responsible entity shall maximize the scope of information in the AA report that can be made available to the public, while maintaining protection of legitimate trade secrets.”

There is also a reference to overall evaluation of performance between alternatives and the priority product with consideration given to the “sensitivity of the comparative evaluation to data uncertainty” in § 69505.4(b)(7). The intent of this phrase is confusing and should be clarified.

IIB. Consortia/Anti-Trust:

Consortia. For consortia of companies, public-private partnerships and trade associations, multiple responsible entities must come together. There can be great benefits to such programs to drive innovation on common problems. However, there are potential anti-trust concerns with organizing such a group to accomplish the AA objectives as envisioned by the Department. For example, although EU's REACH allows data sharing within Substance Information Exchange Fora (SIEF), data are limited to human and environmental toxicity, exposure patterns and safe practice considerations only. In contrast, the scope of the AA as described by DTSC involves company decisions on alternative selections (i.e., business plans) based on a myriad of factors beyond hazard information. The Department proposes to require a number of elements in the Alternatives Analysis Report that a consortium of companies, a public-private partnership, or a trade association would not be permitted to discuss, evaluate and report on because of Federal antitrust restrictions. Among those restrictions are the communication or exchange of confidential competitive information (69505.4(a)(2)(B)1. and 2.), discussion of prices of ingredients or products and internalized costs to businesses (Section 69505.4(a)(2)(B)3. and (C)), and discussion of business plans (Section 69505.4(c)).

A new section in the draft regulations, 69505.1 (c)(1), seems to address this concern, allowing a company to fulfill all of its obligations, or to allow the company to fulfill some of the obligations while having another person fulfill the rest of the requirements in lieu of the company. We support this .

III. Alternatives Analysis Reports

(i) **Focus on Designated Chemical of Concern and Alternatives.** Regarding list of chemical ingredients in Priority Product (PP) and potential alternatives, sections that make reference to the need for a complete list or analysis of all chemical ingredients within the PP beyond the designated CoC should be deleted (i.e., § 69505.5.(i)(2)(C) under "Supporting Information" AND § 69505.5.(j)(2)(C) under "Selected Alternative"). As described above, a list of other chemical ingredients in products is not necessary for the successful analysis of the Chemical of Concern and its alternatives. To avoid detracting from the intent of the statute, the focus should remain on assessing the identified CoC and its alternatives, NOT all chemicals within a product.

(ii) **Compliance with law.** Within the Implementation Plan (§ 69505.5.(k)(2)(A)), the proposed text refers to any steps necessary to ensure compliance with applicable federal, state, or local laws. This provision should be expanded to include **international** laws as well. Since companies operating within the U.S. often make and market products for all of North America, compliance with Mexico and Canada's requirements may also be necessary (e.g., a New Substance Notification (NSN)).

(iii) **Focus on Designated Chemical of Concern and Alternatives.** In § 69505.5.(k)(2)(B)), since the driver of the AA is the CoC identified by the Department as the basis for a product being listed as a priority product, and the focus of the AA was the development of alternatives for that specific CoC/PP pair, the manufacturer's proposed regulatory response should focus on the outcome related to that specific CoC/PP pair. It should not attempt to sweep in other potential CoC that were not the focus of the AA. All language relating to product's contents beyond the CoC(s) that was/were the basis for the listing should be deleted from this Article. We propose that the language be revised to reflect this:

“§ 69505.5.(k)(2)(B)), The implementation plan may also include the identification of any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, ~~any~~ **the Chemical(s) of Concern, that is/are the basis for designation of a product as a Priority Product**, that will be in the selected alternative or that is in the Priority Product **above the AA threshold** if the decision resulting from the AA is to retain the Priority Product.”

IV. Regulatory Treadmill

The regulation as written could end up regulating the same product incessantly without significant improvement to public health or the environment.

As written, a priority product is identified based on CoC(s) selected by the Department. That CoC/PP pair undergoes alternatives analysis to identify potential alternatives. Even after replacing the CoC with an acceptable alternative, the product is still a Priority Product forever. Having focused on the product for several years, the Department will be biased to continue focusing on the Alternative Product to prioritize it again as a Priority Product. As we heard at the December 8 (2011) legislative oversight hearing on Green Chemistry, Dr. George Daston (P&G) commented that “definitive results” would be a successful criterion, without the need for further regulation of the alternative.

This regulatory treadmill will kill innovation, diverting company resources to continuously assess a product that is already safe, preventing the development of other improvements in safety, cost and sustainability. Companies devote substantial resources to ensure the safety of their products, with intentionally-added chemicals and incidental contaminants well below a safe threshold level. We urge the Department to narrow their focus on CoC/PP use pairs that truly contribute to significant adverse impacts on public health and the environment, and for which an alternatives analysis would be beneficial and would improve the safety profile for public health and the environment. When definitive results have been achieved, the Department should declare success. The company’s product should no longer be a Priority Product, and DTSC should move on to other PP/CoCs.

§69506. Regulatory Responses.

GMA continues to have serious concerns with the Regulatory Response section. The proposed regulation does not provide standards for decisions by the department and in several cases exceeds the authority provided in the Statute.

Section 69506. Regulatory Response Selection Principles.

Subdivision (a) provides that the Department shall identify and require implementation of regulatory responses that “maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.” Subdivision (b) provides that in selecting regulatory responses, the Department shall give preference to responses “providing the greatest level of inherent protection.” Inherent protection is defined to mean “avoidance or reduction of

adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls.”

These provisions of section 69506 seem to conflict with the statutory provision in section 25253. There, the Legislature has established the standard for evaluating chemicals of concern in consumer products and their potential alternatives “to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.” Limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection.

Section 69506.2. AA Report Supplemental Information Requirements.

This section provides that the Department may, at any time, require a responsible entity to provide information supplementary to the final AA report for the Department to select and ensure implementation of one or more regulatory responses or to fill one or more of the information gaps identified in the final AA report if the Department determines the information is needed to evaluate the initial regulatory response. It is significant to note that this section contains no standards when the Department will or will not choose to require supplemental information to be provided. It gives them complete unfettered and arbitrary discretion.

Section 69506.3. No Regulatory Response Required.

This section provides that no regulatory response is required if the Department determines that no regulatory response is necessary to prevent or limit adverse public health and environmental impacts. Perhaps the Department believes that referring to preventing or limiting public health and environmental impacts is an adequate standard, but the truth of the matter is that it is little more than a tautology. That is, no regulatory response is required if the Department determines that no regulatory response is required. This section would have much more meaning if standards were spelled out.

Section 69506.4. Product Information for Consumers.

This section applies to "selected alternative products, Priority Products for which an alternative is not selected, and Priority Products which remain in commerce in California pending development and distribution of an alternative product for longer than twelve (12) months." In other words, it applies to all products going through the AA process.

It should be noted that this section does not contain the same provision as sections 69506.6, 69506.8, stating “except as provided in section 69506.3” the requirements apply. The absence of that provision in this section as well as sections 69506.5 and 69506.7 might not in and of itself pose a serious problem because section 69506.3 states that no regulatory response under section 69506.4 through 69506.10 is required if the Department determines that no regulatory response is necessary. However, the presence of the “except” provision in sections 69506.6 and 69506.8 creates an ambiguity as to why that provision is not also included in sections 69506.4, 69506.5, and 69506.7. Does the drafter of the regulation intend to imply something different?

This section requires substantial information to be made available to consumers prior to exposure to any chemical of concern. The information is to be made available through the manufacturer’s website and either through product packaging or written materials

accompanying the package, or posting in a prominent place at the point of retail display. A substantial question exists as to whether the requirement of posting information on product labeling or in inserts is feasible. Also, how are the retailers reacting to the requirement to post substantial information at the point of display?

Section 69506.5. Use Restrictions on Chemicals of Concern in Consumer Products.

As noted with respect to section 69506.4, this section does not include the provision, “except as provided in section 69506.3.” The same point made with respect to section 69506.4 applies here.

In addition, this section imposes restrictions on the use of one or more chemicals of concern and a selected alternative or in a priority product for which no alternative is selected or on the use of the product itself. The section spells out what the use restrictions may be, but it contains no standards as to when these restrictions may be imposed. The section simply says, “The Department may impose restrictions.” Again, the Department has conferred unfettered and potentially arbitrary discretion on itself.

Section 69506.6. Product Sales Prohibition.

Subdivision (a) of this section provides that the section does not apply to a product that does not contain any chemical of concern above the applicable alternatives analysis threshold. Subdivision (b) provides “except as provided in section 69506.3” a sale prohibition may be imposed if a selected alternative contains one or more chemicals of concern or if no alternative is selected for a priority product and “there is a safer alternative that does not contain a chemical of concern and that is both functionally acceptable and technically and economically feasible.”

Perhaps a sales prohibition is appropriate in the circumstances set out in subdivision (b). However, note that subdivision (d) provides that the Department may issue a notification prohibiting the sale of a product “notwithstanding that there are no current identified safer alternatives that are both functionally acceptable and technically and economically feasible.” Subdivision (d) contains no standards as to when the Department would issue a notification prohibiting the sale.

It should be noted that subdivision (d) supersedes subdivision (b) by allowing the Department to prohibit the sale whenever it chooses. Again, the absence of any standard enables the Department to impose unfettered and potentially arbitrary discretion.

Section 69506.7. Engineered Safety Measures or Administrative Controls.

This section, like section 69506.4 and 69506.5 do not contain the provision “except as provided in section 69506.3.” Again, an ambiguity is created by its absence.

This section allows the Department to impose requirements that control access to or limit exposure to chemicals of concerns, to reduce the likelihood of adverse public health and/or environmental impacts. Subdivision (b) of this section sets out three circumstances when engineering or administrative controls may be imposed by the Department. The question is whether those standards make sense in the context of the regulatory response.

Section 69506.8. End of Life Management Requirements.

As noted before in some of the earlier drafts, the EPR program set out in this regulation is Cal Recycle's dream program. It includes many of the provisions that Cal Recycle sought to obtain in legislation two years ago and, more recently, sought to impose in regulations in two statutorily mandated EPR programs. A significant requirement, for example, is that compensation must be provided to retailers who agree to administer or participate in the collection program.

In subdivision (c), the Department apparently seeks to exempt existing EPR programs. However, it does not state it specifically. Rather, it authorizes the responsible entity to substitute an alternative end of life management program that achieves "to the maximum extent feasible, the same results as the program required by this section." It provides that a responsible entity may not substitute an alternative end of life management program unless it receives advanced written approval from the Department. Hence, the paint program could be stuck with both an end of life management program administered by DTSC as well as by Cal Recycle. Such regulatory duplication is prohibited under the statute.

Section 69506.9. Advancement of Green Chemistry and Green Engineering.

This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals. No standards are set out as to when the Department would do that. Again, that Department has conferred on itself unfettered and potentially arbitrary discretion.

Section 69506.10. Regulatory Response Selection and Reevaluation.

Subdivision (a) of this section provides that the Department may impose one or more regulatory responses specified in the preceding sections to situations other than those specified in those sections. As noted before, many of those sections do not contain specified situations. But here, the Department has conferred complete discretion on itself to impose any regulatory response under any set of circumstances that it may choose. The Department goes on to say that the Department may periodically reevaluate any regulatory response to determine if changes are needed based upon changed circumstances or information.

Section 69506.11. Exemption from Regulatory Response Requirements.

This section is ostensibly designed to implement the provision in section 25257.1 of the statute.

Subdivision (b) of the statutory section provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides that, "The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

Section 69506.11 of the regulation puts the burden on the responsible entity to apply to the Department for an exemption. The exemptions are to be based on a conflict of one or more requirements of another California or federal regulatory program. The second basis for an exemption is that the proposed regulatory response "substantially duplicates" one or more

requirements of another California or federal regulatory program, “without conferring additional public health or environmental protection benefits.”

Three points need to be made with respect to this section. First, nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department, providing the article does not authorize the Department to supersede, duplicate, or adopt conflicting regulations. The Legislature has imposed responsibility on the Department to implement that provision. It does not contemplate imposing the burden on responsible entities.

The second point to be made is with respect to paragraph (6)(B) of subdivision (a), limiting the exemption of substantially duplicating one or more requirements of another regulatory program to circumstances where the proposed regulatory response does not confer additional public health or environmental protection benefits. Again, this exceeds the Department’s authority. Nothing in this section with respect to duplication contemplates that DTSC or the Department may duplicate other regulatory programs if the Department is conferring greater public health or environmental protection.

The third point to be made with respect to this section is that once again the Department has ignored the fact that subdivision (b) of section 25257.1 prohibits the Department from superseding the regulatory authority of any other department or agency. By imposing a program, even if it provides additional public health or environmental protection, supersedes the other agency’s regulatory program. The Department is specifically prohibited by section 25257.1 from doing that. Yet, nothing in the regulation acknowledges that.

Section 69506.12. Regulatory Response Report and Notifications.

This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. The balance of this section sets out when and how that notification is to be provided. A substantial question exists as to whether this requirement is authorized by the statute. Section 25253(b) of the statute provides that the regulations adopted pursuant to this section shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. The notification to the retailers is not designated as a regulatory response. Rather, it is applied to a responsible entity after a regulatory response is imposed on that entity. Nothing in the statute authorizes the Department to impose such a reporting requirement. It exceeds the scope of the authority to specify the range of regulatory responses.

§69507. Dispute Resolution Process.

Section 69507. Dispute Resolution.

Under the provisions of this section, the dispute resolution process does not apply to decisions made by the Department under Article 2, Chemicals of Concern Identification Process, Article 4, Petition Process for Identification and Prioritization of Chemicals and Products, or Article 10, Trade Secret Protection. Disputes in those cases must be taken up in a judicial proceeding.

Section 69507.1. Informal Dispute Resolution Procedures.

This section provides that the informal dispute resolution procedures apply to all decisions made by the Department other than those made under sections 69506.5, 69506.6, 69506.7, 69506.9, 69506.10, and 69506.11. All of those sections are in the regulatory response category and disputes of those decisions are dealt with in the formal dispute resolution procedure. That means that at least three of the regulatory responses described in Article 6, are to be dealt with through the informal dispute resolution procedures. Those include section 69506.2, the requirement for responsible entities to provide supplemental information, section 69506.4 requiring that product information be provided to consumers, and section 69506.8 requiring responsible entities to set up an end of life management program.

All regulatory responses should be subject to the formal dispute resolution process. Certainly, the end of life management is a significant one that perhaps should be resolved through the formal dispute resolution rather than the informal process.

The effect of failing to pursue one of these dispute resolution procedures is unclear. The regulation specifies that if a request for dispute resolution is not received within a certain time period, “the Department’s decision is final and is not eligible for any dispute resolution procedures under this article.” Does the Department intend that the failure to pursue an administrative dispute resolution procedure precludes the responsible entity from seeking review of the Department’s decision in a court?

It appears that the proposed regulation attempts to avoid that issue by simply saying that there are no further administrative review procedures. It does not specify whether that cuts off judicial review. This must be clarified in the final regulations.

§69508 Alternative Analysis Certification

(i) Accreditation Bodies—Quality Assurance for Alternatives Analysis

Although it appears that criteria by which a body becomes an accreditation body are not explicit in the draft regulations, qualifications and expertise required as noted in §69508.1 are adequate and necessary to designate an entity as an accreditation body. Due to the complex nature of any AA, the availability and accessibility to a wide range of expertise in various scientific fields are instrumental to a successful accreditation body. Broad skills and knowledge are required to conduct analysis across the extremely broad spectrum of products, chemicals, evaluation factors and impacts that would need to be assessed in AAs as envisioned by this regulation. One area of practice that seems to have been omitted but should be included in 69508.1(a)(5) is Exposure Assessment. Key technical skills beyond exposure assessment that are required to develop safe and effective products for consumer use include toxicology, environmental toxicology, chemistry, chemical engineering, microbiology. In addition, the process will require the help of those knowledgeable in finance/accounting, life cycle analysis, and consumer and clinical testing.

The only overarching concern is that if these entities do not include a wide range of expertise from product and chemical manufacturers, then they may never appreciate the intricacies of product development and R&D and be able to convey the nuances inherent in product development within specific industry sectors to applicants.

Nevertheless, the accreditation body should focus on training would-be assessors as project managers. The certified assessor should only be responsible for ensuring that all expectations and requirements for the AA have indeed been addressed. The certified assessor should rely on subject matter experts in the various fields and disciplines to provide the necessary information on relevant factors within an AA.

(ii) Certified Assessors

In-house company experts with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead alternative analysis projects for product development and should not have to become certified assessors, or should be certified with minimal requirements based on their experience. An R&D scientist must consider a variety of factors in the selection of chemical ingredients for a consumer product. The safety of an individual chemical and life cycle considerations are only pieces of the equation. Chemical ingredients often serve multiple functions in a consumer product formulation rather than provide a single benefit. Therefore, Alternative Analysis is a broad process that must evaluate a number of holistic considerations for any potential chemical alternative, including impact on safety and product performance, potential interaction with other formula components, useful life, other environmental criteria, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right combination of chemical ingredients for consumer product formulations. In-house company experts appreciate the intricate R&D science invested in developing consumer product formulations and have the necessary in-depth understanding of consumer behavior and preferences.

Certification, however, should be invested in those individuals charged with overseeing the various aspects of the alternatives analysis and with ensuring successful execution in meeting the Department's requirements. As discussed, an in-house certified assessor is well positioned to understand how to apply an AA to a Chemical of Concern/Priority Product pairing, with a variety of available experts utilized to address specific aspects of the AA. Product development experience should play a significant role in the time and effort necessary for certification. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors' work products) that is being certified. DTSC should have the ability to challenge the Accreditation body.

The provision for "Random auditing by the accreditation body or its consultants to ensure the quality of work and proper application of tools by the assessor" (§ 69508.2 (c)(7)(C)) would satisfy quality assurance concerns.

(iii) Audit

GCA agrees that beyond good AA Guidance, DTSC audits, particularly in the early years of implementation, will help to increase credibility of the AA process as well as to improve consistency.

§69510. Trade Secret Protection.

Protection for Trade Secrets and Intellectual Property is a core component of this law and is supported by existing California statute and regulations. The proposed regulation includes several aspects that conflict with and/or exceed statutory authority as detailed below.

GMA emphasizes that product formula information in particular is a critical part of a company's trade secrets. The names, concentrations, and physicochemical properties of ingredients in formula will inevitably be claimed secret under this provision and are the result of investments in innovation. The time-frames for such claims will regularly extend well beyond a few years—such innovations are often core to a product's success for decades. Each innovation can build on and enhance previous innovations and must be protected from disclosure to competitors. It should come as no surprise that substantial portions of AA reports, especially data-based, detailed comparisons, will be redacted for these reasons and more.

GMA strongly opposes a new provision, eliminating protection for chemical identity in connection with the submission of hazard trait information. This is an unnecessary and exceeds the department's authority under the statute. Chemical identity should always be claimable as a trade secret. From a legal standpoint, hazard information is distinct from Chemical identity. Traditionally, generic chemical names are provided in connection to the hazard information, which are sufficient for meeting statutory requirements and enabling an appropriate level of public information for the safe use of chemicals. From a policy standpoint, asking companies that have invested millions of dollars on the development of new technologies and products to make them public and benefitting competitors, makes no sense.

Aside from trade secrets, manufacturers should not have to jeopardize their ability to file patents, particularly under the new "first to file" patent regulations to be in effect soon. One key tenet of the new legislation is that the priority date for a patent claim will be awarded to the "first to file" a provisional patent application, not the "first to invent (previously substantiated with a standard affidavit of, for example, a witnessed lab notebook)". Thus, if a manufacturer's alternative is declared in the report and disclosed publicly, the manufacturer's invention would be precluded from intellectual property protections. Disclosure of proprietary raw material considerations, compositions, processes, use methods, technology, etc. must keep the filing of patents in mind. Even the disclosure of a particular raw material as an alternative to a chemical of concern in a particular product could be considered the sort of public disclosure that impacts patent rights, if not in the U.S., then potentially in other jurisdictions since it becomes public knowledge at that point. Allowances for confidential disclosure with the agency must be made clear in the regulations.

Section 69510. Assertion of a Claim of Trade Secret Protection

Subdivision (a) requires an entity making a claim for trade secret protection to provide specific information. The proposed regulation contains the same provisions that GMA has objected to previously. Here, they are set out as paragraph (6), the estimated value of the information to the person and the person's competitors; (7) the estimated amount of effort and/or money expended by the person in developing the information; and (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering.

In addition, paragraph (10) requires, a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed.

Further, paragraph (11) requires the signature of the person's general counsel or other executive, certifying under penalty of perjury that there is a basis for asserting a trade secret protection.

Subdivision (c) requires in paragraph (2) a redacted copy of the documentation being submitted which shall exclude the information for which trade secret protection is claimed. The Department may make the redacted copy of the documentation available to the public at its discretion. GMA opposes the submission of redacted copies. In addition, the last provision, making the redacted copy available at the discretion of the Department is inconsistent with the provision in Section 69501.5 (b) (6) where it says it "shall" put on its website "a full or redacted copy of each document."

Subdivision (e) provides that if the documentation supporting the claim of trade secret contains information that is itself trade secret, the supporting documentation shall be supplied in both the complete and redacted form.

Subdivision (f) ostensibly is included to implement the provision of the statute providing that the section on trade secret protection "does not apply to hazard trait submissions for chemicals and chemical ingredients pursuant to this article." Subdivision (f) specifically says that trade secret protection may not be claimed for any health, safety, or environmental information contained in any hazard trade submission or any chemical identity information associated with a hazard trade submission. The chemical identity portion of the regulation arguably exceeds the scope of the statutory authority, which only precludes protection for hazard trade information, not chemical identity.

Subdivision (g) provides that trade secret protection may be claimed for the chemical identity of a chemical that is the subject of a hazard trait submission only if the claim is for a proposed alternative to a chemical of concern in a priority product subject to certain requirements. Those requirements include demonstrating to the Department's satisfaction the chemical is a new chemical or a new use of an existing chemical, providing the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing chemical of concern of the priority product, and complying with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret.

Hewlett-Packard Company
8000 Foothills Blvd., MS/5580
Roseville, CA 95747
US

www.hp.com



October 11, 2012

Deborah O. Raphael, Director
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, CA 95812-0806

RE: COMMENTS ON SAFER CONSUMER PRODUCT ALTERNATIVES PROPOSED REGULATIONS

Dear Director Raphael:

Thank you for the opportunity to review and comment on the California Department of Toxic Substances Control's (Department or DTSC) July 2012 proposed Safer Consumer Products (SCP) regulations (Proposed Regulations).

Hewlett-Packard (HP) strongly supports the goals of Assembly Bill (AB)1879 and believes that the selection of good alternatives to Chemicals of Concern (CoC) is an essential step in reducing potential risks to public health and adverse impacts on the environment. HP has a long history of "green chemistry" and environmental initiatives, and we hope that our perspectives and experiences can help the Department's efforts in making this a successful program.

Based on HP's work on evaluating alternatives to restricted substances, the most critical areas in need of adjustment are listed below. HP's recommendations the following:

- Establish a Department-facilitated, multi-stakeholder Alternative Assessment (AA) as the baseline AA process, with the currently proposed individual AAs available to entities wishing to opt-out of the State-led AA
- Ensure that deadlines, requirements, and regulatory responses will be applied uniformly to all affected responsible entities
- Eliminate the certified assessor program and review the submitted AAs in aggregate in order to inform the regulatory response
- Focus Phase 2 of the AA on identifying unacceptable burden-shifting of alternatives

James Wilie

Environmental Compliance Program
Manager

T 916-785-2981

F 916-231-1346

james.wilie@hp.com

We have also prepared a list of additional comments of the Proposed Regulations that are in the attachments (Attachments 1 through 7).

DTSC Should Establish Department-Facilitated Public AAs as the Primary Mechanism to Collect Information Required by AB1879 to Support Appropriate Regulatory Responses on CoC in Consumer Products

The Proposed Regulations establish a very inefficient system to gather the necessary information to make sound regulatory decisions. The structure currently envisioned includes the following problematic, resource-intensive features:

- Each responsible entity must complete a separate AA, leading to:
 - Duplicated effort to generate similar data; and
 - Potentially poor quality AAs because of a lack of subject matter expertise and resources at affected companies, necessitating a cumbersome assessor certification scheme;
- The Department is burdened by having to review large numbers of AAs with similar content with varying degrees of quality, while also requiring the oversight of a complex assessor certification and accreditation bodies program to review those same AAs;
- The Department must manage and respond to thousands of notifications per CoC/Priority Product combination. For example, within the consumer electronics industry, there are hundreds of companies that could be affected by a listing of Bis-ethylhexyl phthalate (DEHP) in wire and cable applications. If each responded independently for each phase of the AA process, as required by the Proposed Regulations, it would flood the Department with thousands of notices, even if most companies completed their assessments collaboratively through consortia; and
- The Department must post large amounts of information on its website that will require constant updates.

The large number of notifications, assessments, and web postings, as well as, the need for overseeing the assessor certification program, will require extensive Department resources that will divert resources from the core mission of gathering reliable data to make good decisions that protect human health and the environment, as envisioned in AB1879. The Department has been clear that it is interested in structuring the program in a way that ensures that its anticipated resources will be sufficient to run the program. Bewilderingly, the proposed program is far more resource intensive than it needs to be when an alternative exists to simplify the structure of the program and increase the quality of the AAs developed by creating a small, central DTSC team capable of facilitating high quality, public AAs.

The key point here is “facilitating.” The Department will not need to become subject matter experts on each formulation question that may arise in an assessment, but rather it must evaluate the technical merits of arguments presented by subject matter experts – a task that the Department must do even under the current

proposal to act on individual AAs and determine appropriate regulatory responses, if any. Based on our experience with similar programs, such as the U.S. EPA Design for the Environment (DfE) program, the technical staff to support a single AA could be as low as 2-3 dedicated headcount, with the bulk of the work being done by participating stakeholders, and experts being consulted as needed.

This proposed change would be good for business because of the significantly greater efficiency. Public AAs would drive innovation by recognizing producers of safer alternatives, and would be especially helpful to small businesses because of the automatic compliance offered by participation.

Additionally, this approach would substantially address many of the non-governmental and academic stakeholder concerns about transparency and peer-review of the AAs. While it may make the process somewhat more contentious to include all stakeholders, the Department would benefit from the critical review provided by the more open debate of the data and findings.

Individually generated AAs are not peer-reviewed, transparent, and do not reflect the perspectives of other important stakeholders, including downstream users. HP has found these features to be absolutely essential in generating accurate and meaningful results upon which to act. See Attachment 8 describing an example of HP's AA program.

A Department-facilitated program would help ensure that the best practices in AA are being broadly applied, establishing California as a leader in the drive toward safer chemicals and products through its state-of-the-art public AA program. Moreover, even if there are multiple AA submissions, HP believes it is critical to ensure fairness that the Department issue a single regulatory response for each CoC/Priority Product combination, based on the aggregate finding of all AAs. Establishing and encouraging a single AA will assist the Department in issuing the single regulatory response that it must develop.

Although there are many ways the Proposed Regulations would have to be modified to restructure the program, listed below is one alternative. Essentially, the Department-led program could be added on top of the program as proposed, with the current system serving as the process for those companies choosing to perform their own AA rather than participate in the public AA.

HP recommends the following:

- Establish a Department-facilitated, public AA program, modeled on the U.S. EPA DfE multi-stakeholder AA program, as the primary mechanism to collect scientifically rigorous, peer-reviewed, transparent information required by AB1879 to support appropriate regulatory responses on CoC in consumer products;

- Eliminate notifications, except in cases where companies choose to complete independent AAs, which would then have to be completed on the same schedule as the public AA;
- At the conclusion of each AA, the Department would consider all relevant submitted information to craft a single, appropriate regulatory response for each CoC/Priority Product combination.

The Proposed Regulations at Section 69305.4 should be modified to add the establishment of a Department-led AA program:

(3) Once a chemical is added to the COC list and determined by the Department to be present in Priority Products for which an AA must be conducted, the Department shall facilitate the performance of an AA for the major use(s) of that COC in the Priority Products.

- (A) The AA shall be open to participation by any interested stakeholder, including manufacturers, distributors, retailers, non-governmental organizations, academic institutions, manufacturer consortia, trade associations, and individuals.
- (B) The Department shall ensure that the AA is conducted such that it meets the requirements of Article 5.
- (C) Participation in the Department-led AA shall not limit a responsible entity from performing a separate AA as described in Article 5.
- (D) Participants in the Department-led AA shall be subject to data call-ins by the Department pursuant to completing the AA, and with provisions for protection of trade secrets as per 69510.

DTSC Must Ensure a Level Playing Field for Responsible Entities

The Proposed Regulations create the potential for dramatically unequal treatment of responsible entities in three critical ways:

- Compliance with notifications and AAs for entities not known to DTSC cannot be enforced;
- Deadlines and extensions for submission of AA Reports may not be the same for all related responsible entities, and
- Different regulatory responses for different responsible entities creates the appearance of impropriety and potential corruption as differing responses are awarded to entities based on hidden criteria.

HP supports all of the concerns on this point submitted to the Department by EU DG Enterprise (G/TBT/N/USA/727 – Draft Regulation of the Californian Department of Toxic Substances Control (DTSC) on “Safer Consumer Products” – EU Comments, dated 11 Sept 2012).

The ability of the Department to enact different regulatory responses for different responsible entities is fundamentally unfair. It also enables the Department to interfere in businesses and the market in very undesirable ways, such as potentially requiring small businesses to allocate large, unsupportable sums to predetermined Research and Development projects.

In addition, the Proposed Regulations do not state clearly that all AA Reports will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all. The Department must ensure that all AA Reports are submitted simultaneously to ensure that entities are on a level playing field, have the same amount of time, and will not be disadvantaged by the Department reviewing AAs successively.

HP recommends the following:

- As discussed elsewhere in these comments, to address the inequity of the initial phases of the program, including notifications and AAs, the Department must facilitate or conduct the primary AA, without requiring individual entities to submit notifications and conduct individual AAs.
- If there are multiple AA submissions, the Department must state clearly in the Regulations that the deadline for submission of AA Reports will be the same for all responsible entities and that any extension granted for one responsible entity will apply for all responsible entities.
- If there are multiple AA submissions, the Department must issue a single regulatory response for each CoC/Priority Product combination, based on the aggregate finding of all AAs. Therefore, if the Department finds that a CoC in a Priority Product requires a regulatory response to protect human health and the environment, the Department must act uniformly in requiring that regulatory response for all affected responsible entities. Likewise, any exemptions should be the same for all responsible entities.

DTSC Can Reduce the Burdens and Wasted Costs of the Overly Complex Accreditation Bodies and Certified Assessors Program Without Compromising the Integrity of the Program

Article 8 of the Proposed Regulations establishes an elaborate, unique credentialing scheme intended to address concerns about the technical rigor of AAs submitted to the Department. The proposed scheme:

- Imposes burdensome requirements for certification that will preclude many subject matter experts from qualifying;
- Virtually requires assessors to be located in California to obtain and maintain credentials, which is extremely challenging to entities with subject matter experts outside of California, including large multinational companies, such as HP;

- Is unlikely to substantially improve the quality of the AAs because good assessments rely on deep subject matter knowledge that credentialed generalists are unlikely to possess;
- Does not build the community of expert practitioners envisioned by the Department because if the program is working properly, there should be no need for multiple AAs of a CoC/Priority Product combination, because all significant issues should have been resolved by the regulatory responses, and thus no need for a standing pool of assessors with expertise in a particular industry or product class; and
- Diverts critical resources from the Department's core mission of gathering reliable data on which to make good regulatory decisions that protect human health and the environment and instead directs them to administering the assessor credentialing system.

A key component of AB1879 is the requirement for the Department to conduct "[the evaluation of] chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern."

Thorough evaluations of CoC and their alternatives are critical to meeting the goals and requirements of AB1879, so understandably the Department wants to ensure the rigor and quality of the AAs that must be conducted. The proposed assessor certification scheme in the Proposed Regulations is clearly intended to help meet this goal. Unfortunately, it misses the mark.

HP acknowledges that the proposed scheme is partially modeled on the Massachusetts Toxics Use Reduction (TUR) Planners from the TUR Act (TURA). Certified TUR Planners have been an important part of the Massachusetts program, which has assisted businesses substantially reduce toxics. However, an understanding of the differences between TURA and AB1879 shows clearly why a certification system that is so useful to one program would not translate to success in the other.

TURA focuses on in-State facilities that manufacture, process, or otherwise use listed substances. These facilities are required to engage in on-going planning to find opportunities for toxics use reduction. It is clearly useful to have a local community of TUR planning experts when the in-scope facilities are in one area and have an on-going need for specialized review and planning services.

In contrast, AB1879's scope encompasses out-of-State producers and focuses on the products themselves and the potential exposure of COCs to consumers, rather than manufacturing processes. It is designed to address and resolve issues associated with particular COC/Priority Product combinations, and is not intended for multiple, iterative review cycles. If the program is working properly, there should be no need

for repeated assessments of a COC/Priority Product combination because all significant issues should be resolved by the regulatory responses, thus eliminating the need for a standing pool of consultants with expertise in a particular industry or product class.

If assessors are intended to be generalists instead of industry experts, there is even less reason to maintain such a program. The issues for each COC/Priority Product evaluation are expected to be vastly different due to the broad definition of consumer products being used (e.g., the scope of AB1879 includes both cars and nail polish). Generalists will be of limited value in these assessments. Companies should be using their best, most knowledgeable staff to conduct these evaluations, even if those people are not in California or do not maintain certified status. Again, if done properly, there should not be a need for multiple assessments on any particular COC/Priority Product combination, and therefore, there would be no need for highly skilled subject matter experts to get or maintain a certification.

Although the TUR Planner system works for TURA, it is not the best model for meeting the requirements of AB1879. It is unlikely to create the highly skilled pool of expert practitioners envisioned by the Department. And although the certified assessor scheme may seem an appealing and feasible way to review AAs and ensure quality assessments, it is not clear that assessors will bring any additional rigor beyond that which can be obtained through the use of subject matter experts so the program will not accomplish that goal. If the argument for certified assessors is based primarily on pragmatism of what can be supported with Department resources, it should be noted that managing a credentialing system in perpetuity is, in fact, very cumbersome, and will consume the Department resources from the central task of reviewing submissions.

One alternative to the certified assessor system that has been proposed is a peer review system, modeled on those used by technical journals. This option has been described and discussed previously in HP's prior comments submitted on February 2012. Such a system would be no more cumbersome to administer than a certified assessor system, yet could provide a much more robust review of assessments to be submitted to the Department. While a peer review system would be an improvement to the certified assessor scheme in that it would significantly improve the likelihood of rigorous assessments being submitted to the Department, it suffers from the same problem of the certified assessor program in that Department resources would have to be used to maintain it at the expense of reviewing actual submissions.

Ultimately, the Department is responsible for reviewing and acting on the findings of the submitted assessments. Any administrative work that distracts or diverts the Department from this work should be eliminated, including maintaining a certification scheme or even administering a peer review system. Focusing on the content and findings of the assessments is essential to meeting the intent of AB1879 and ensuring that credible information is used as a basis for regulatory responses.

Additionally, if the Department alone reviews submissions, it will be in a much better position to safeguard any confidential business information submitted in assessments. Moreover, there are significant revisions to the Proposed Regulations that HP has described in its comments that if implemented, will reduce the number of AAs and further reduce the need for this assessor program.

HP recommends the following:

- Article 8 and all associated references to certified assessors should be eliminated.
- No certification should be required for generating and submitting assessments.
- The rigor of the assessments should be ensured through direct review by the Department.
- If the Department will not eliminate the assessor scheme, then the requirements and burdens of certification should be lightened to the maximum extent possible to allow subject matter experts to become easily certified, complete and submit their assessments, and then let their certifications expire, when no longer needed. Specifically:
 - Section 69508(a) should be deleted;
 - Section 69508(b) should be reduced to a simple computer –based training module with a challenge test to be certified;
 - Section 69508(c) can be retained if it is clarified that the challenge test part of the computer-based training can be completed online;
 - Sections 69508(d)-(g) can be retained;
 - Section 69508.1 should be modified so the requirements are reduced and accreditation bodies are not limited to California universities.
 - Sections 69508.3 and 69508.4 can be retained.

DTSC Should Allow Responsible Entities to Select Multiple Alternatives in Phase 2 AA without Department Approval

Phase 2 of the Alternatives Analysis forces responsible entities to select and implement a single alternative to a CoC in a Priority Product, notify the Department if another alternative is later used, and requires that the Department approve replacements. By forcing a single alternative to be chosen and by inserting the Department into the selection process, the following issues are created:

- Potentially forces the use of an inappropriate or suboptimal solution since the Department does not have subject matter experts on staff qualified to

assess the suitability of alternatives from any other perspective than potential impact to human health and the environment;

- Creates the risk that environmentally preferable alternatives may not be adopted or fully developed because they may not be cost effective at first; and
- Fails to take advantage of the resourcefulness of the supply chain to find innovative and cost-effective solutions.

The selection of a single alternative and required notification of another alternative that is used is a highly undesirable situation, because manufacturers use materials and components from different suppliers, and different suppliers may have different optimal solutions. When AAs can identify multiple alternatives that would be acceptable with respect to the impacts to human health and the environment, there is no benefit to artificially restricting CoC replacements to a single alternative.

The only criteria for eliminating an alternative from consideration should be evidence of significant and unacceptable burden-shifting within the environmental or human health criteria. Any less hazardous option, as identified in Phase 1, that shows no significant burden-shifting in the A-M criteria in Phase 2 should be allowed as a potential replacement.

Complex supply chains can often support multiple replacements for CoCs. For example, when Pb solder was restricted in the Restriction of Hazardous Substances (RoHS), many different solders were developed and commercialized to replace Sn-Pb eutectic solder. Phase 2 should focus strictly on the elimination of options showing unacceptable burden-shifting. This will allow suppliers to find the most cost-effective and innovative solutions. The Department's role should be to review the findings with respect to burden-shifting among the A-M criteria, looking for alternatives with unacceptable trade-offs for elimination, but otherwise to allow companies to find solutions that work for them.

On a related point, an economic analysis should only be required if a responsible entity is attempting to justify continued use of a CoC. Economic analyses as described in the Proposed Regulations are extraordinarily difficult to complete, and serve no purpose once the question of burden-shifting is addressed. As long as the alternatives being considered are less hazardous, as determined in Phase 1, and don't show unacceptable burden-shifting in Phase 2, no economic analysis should be required for the purposes of the AA. Companies are best able to address cost differences between various acceptable alternatives and the Department must not be involved.

October 10, 2012

HP recommends the following:

- To facilitate multiple alternatives, Section 69505.2.(d) should be eliminated and 69505.4(c) and 69505.5(j)(2) should be modified to allow multiple alternatives to the CoC.
- To reduce the burden of the economic analysis section of the AA, Section 69505.4.(a) (2)(C) should be modified to clarify that economic analysis is only required when a responsible entity is seeking continued usage of the CoC, and that no analysis is required otherwise.

HP appreciates the opportunity to comment on the Proposed Regulations and recognize the Department's difficult work in developing the Proposed Regulations. HP looks forward to working with the Department in creating a balanced regulation that meets the goals of AB1879.

Regards,



James Wilie
Hewlett-Packard
Environmental Compliance Program Manager

Cc: Jennifer Morris, HP
Helen Holder, HP
Jon Dickinson, HP

Attachments

**ATTACHMENT 1
ARTICLE 1 COMMENTS**

Article 1 - General			
Section	Title	Comment	Proposed Text
§ 69501.1(a)(2)	Accreditation Body	As discussed in more detail in HP's October 11, 2012, letter comments, HP strongly urges DTSC to delete the accreditation bodies procedures and thus this definition should likewise be deleted.	Delete Section 69501.1(a)(2) in its entirety.
§ 69501.1(a)(11)	Alternative	HP supports the change proposed by DTSC that expands the definition of "Alternative" to include alternatives resulting from the removal of a substance and adjusting the ratio of remaining chemicals.	
§ 69501.1(a)(12)	Alternatives Analysis	"Alternative Analysis" is currently defined as: "an evaluation and comparison of a Priority Product and one or more alternatives to the product, under article 5." The current definition of AA misstates the core concept by stating that the AA is intended to evaluate alternatives to the product itself. AB 1879 requires DTSC to "establish a process for evaluating chemicals of concern in consumer products." An AA should be defined as an evaluation of a CoC and its functionally equivalent alternatives in a consumer product.	§ 69501.1(a)(12) "Alternatives Analysis" or "AA" means an evaluation and comparison of Chemical(s) of Concern within a Priority Product and one or more alternatives to the product Chemical(s) of Concern , under article 5.
§ 69501.1(a)(13)	Alternatives Analysis Threshold	HP understands the flexibility that DTSC is seeking to set appropriate thresholds based on the specific toxicity of a CoC at issue and the particular exposure scenarios of the Priority Product containing that CoC by developing individual "Alternatives Analysis Thresholds." HP also believes that, pragmatically, the development of each AA Threshold will be very challenging and will consume enormous, potentially unnecessary, DTSC resources. Having a starting point (default) threshold for triggering AAs, which can be modified as necessary, may make the process for setting AA Thresholds less challenging. Defaults are used in well-developed regulatory systems around the world and provide needed guidance for companies trying to reduce concentrations and exposures. A default will also facilitate a more reasoned discussion about the potential impact of a particular CoC instead of triggering an automatic drive to the minimum detectable concentration, which will not be necessary in many cases. To achieve a default level that may be acceptable to a greater number of stakeholders, HP could support a default threshold of 100 ppm that could be adjusted higher or lower based on reliable information.	(13) "Alternatives Analysis Threshold" means a concentration less than or equal to 100 ppm that can be adjusted higher or lower based on reliable information by weight specified by the Department under section 69503.5(c).
§ 69501.1(a)(14)	Alternatives Analysis Threshold Exemption Notification	As discussed in more detail in HP's comments for Section § 69503.6, HP urges DTSC to delete AA Threshold Exemption Notifications and thus this definition should likewise be deleted.	Delete Section 69501.2(a)(14) in its entirety.
§ 69501.1(a)(18)	Certified Assessor	As discussed in more detail in HP's October 11, 2012, letter comments, HP strongly urges DTSC to delete the certified assessor procedures and thus this definition should likewise be deleted.	Delete Section 69501.2(a)(18) in its entirety.
§ 69501.1(a)(31)	Functionally acceptable	The definition of "functionally acceptable" lowers the performance requirement of alternatives and raises some confusion between this term and "technically feasible." Any alternative must do more than work "sufficiently well" and there must be a higher standard than a belief that consumers can be "reasonably anticipated to accept the product in the marketplace."	§ 69501.2 (a)(31) "Functionally acceptable" means that an alternative to a Priority Product meets both of the following requirements: (A) The product complies with all applicable legal requirements; and (B) The product meets the performance and functionality requirements of the Priority Product. performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.
§ 69501.1(a)(34)	Homogeneous material	HP supports the definition of "homogenous material" as an option for defining thresholds for substances in assembled products because it allows COCs to be narrowly targeted to the materials of interest without setting inappropriately low AA Thresholds. It also allows industries, such as the electronics industry, to use compliance data and analytical test results from existing frameworks that reference homogenous materials, such as RoHS. HP understands that ITI and other OEMs agree on the concept of targeting materials, but have suggested revisions regarding the component and/or homogeneous material definition. HP can support the current or ITI revised definition.	

**ATTACHMENT 1
ARTICLE 1 COMMENTS**

Article 1 - General			
Section	Title	Comment	Proposed Text
§ 69501.1(a)(56)	Safer Alternative	HP suggests revisions to the definition of "safer alternative" to more accurately state what should be considered an alternative that is "safer" than a COC. In addition, HP notes that the Department is not referencing this term appropriately in the Proposed Regulations. Two main places in the Proposed Regulations that uses the term "Safer Alternative" are in Sections 69502.2(b)(4) and 69503.3(d). As discussed elsewhere in these comments for Section 69502.2(b)(4), HP recommends that the Department delete this Section because the existence or not of a "safer alternative" should have no bearing on whether a chemical is identified as a COC. In addition, it is inappropriate for the Department to make its own determinations about the potential existence of a "safer alternative," that requires further determinations of whether a product is "functionally acceptable and technically and economically feasible" before even listing a Priority Product. On the other hand, the term "safer alternative" is not used once in Article 5 with regard to how AAs are conducted and alternatives selected.	(56) "Safer alternative" means an alternative that, in comparison to the COC in with the existing Priority Product: (1) , reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce has less adverse public health and environmental impacts; (2) has no unacceptable level of burden shifting; and (3) is technically feasible.
§ 69501.1(a)(59)	Technically and economically feasible alternative	HP is very concerned that the definition of "technically and economically feasible alternative" is too subjective and provides no sound criteria for determining such a criteria. Without an objective meaning or measure for this definition, it will be difficult to determine when DTSC would consider an alternative to be "technically and economically feasible." For example, the phrases "meeting consumer demand after an appropriate phase in" and the "manufacturer's operating margin is not significantly reduced" have little value when terms like "appropriate" and "significantly" are open to different interpretations. There are other ways to define "economically feasible," in a quantifiable way, such as "does not increase the aggregate cost to consumers." Moreover, the determination of the availability of a "technically and economically feasible alternative" is conducted during Step 1 of the AA's second stage. The regulations for this same stage and step already include a separate analysis of "economic impacts," however. See Section 69505.4(a)(2)(C). To rectify these issues and allow DTSC and affected entities to understand what is a technically and economically feasible alternative and when such determinations must be made, HP recommends the following: (1) separate the definitions for "technically feasible" and "economically feasible" and provide more objective criteria for what is economically feasible; (2) seek information on "economically feasible" alternatives only as part of the "Economics Impacts" of Section 69505.4(a)(2)(C); and (3) require an "Economics Impacts"/"economically feasible" assessment only for AAs when cost is used as a criteria for continuing use of a COC.	
	Mode of Action	"Mode of action" is an important concept in risk evaluation and cumulative risk. This definition should be restored and it should be used as part of a defined risk evaluation process for determining any AA Threshold level.	
§ 69501.2(a)(53)(B)	Reliable information demonstrating the occurrence of exposures to a chemical	Biomonitoring data that may be considered reliable includes information from either of the following: 1. California Environmental Contaminant Biomonitoring Program; or 2. Center for Disease Control's National Health and Nutrition Evaluation Survey biomonitoring data. HP recommends that DTSC include biomonitoring data from other states and Europe that meets the test of reliable information. Biomonitoring data are too scarce to rely solely on data from California.	
§ 69501.2(a)(2)	Duty to Comply and Consequences of Non-Compliance	HP suggests that the Department explicitly clarify which notices must be filed directly by responsible entities and which can be filed on their behalf. The Section cites only two notifications that are required to be submitted specifically by the responsible entity: § 69503.6 (Alternatives Analysis Threshold Exemption Notifications) and § 69503.7 (Priority Product Notifications). Section 69501.3(c) and the corresponding discussion in the Statement of Reasons seems to indicate that a responsible entity would need to make a certification, and thus perhaps the submission, for more notifications than specified in Section 69501.2(a)(2).	
§ 69501.2(b)(1)	Priority Product Removal Notification	Priority Product Removals should be self-implementing and require no notice to the Department. If a responsible entity no longer places a Priority Product into the stream of commerce in California, it should not be penalized by requiring the preparation and submission of a Notification. By eliminating this Notification, DTSC would provide an incentive to remove Priority Products from the stream of commerce of California as well as reduce DTSC's costs and obligations to implement this program. Although not related to this Notification Provision, AB 1879 does task the Department in other contexts to "minimize costs and maximize benefits for the state's economy." Eliminating the Priority Product Replacement Notification is a simple means to reduce the Department's regulatory burden without compromising the integrity of the program. These advantages outweigh any perceived benefit for DTSC to obtain information regarding Priority Products that are no longer in commercial distribution in California.	Delete Section 69501.2 (b)(1) in its entirety.

**ATTACHMENT 1
ARTICLE 1 COMMENTS**

Article 1 - General			
Section	Title	Comment	Proposed Text
§ 69501.2(b)(2)	Priority Product Replacement Notification	This section is unnecessary and should be removed. Any new product containing a COC that is the same or similar to a Priority Product would be considered a Priority Product, such that a responsible entity would need to submit a notification when that new Priority Product is introduced and be responsible for conducting an AA, or if a regulatory response has been already enacted, be subject to that response. This Section shows a distrust of potentially responsible entities that is not warranted.	Delete Section 69501.2.(b)(2) in its entirety.
§ 69501.2(a)(??)	Assembled Product	HP suggests deleting the definition for highly durable products and reinstating the now-deleted definition for assembled product. HP understands the Department's desire to distinguish between Priority Products types and provide some boundaries for how AAs will be conducted for complex products, but the definition provided does not accomplish the Department's goal by including the requirement that entities demonstrate that the product is intended to have "a useful life, or an average useful life, of five (5) or more years." This requirement may exclude many complex products because the type of information required (<i>i.e.</i> , warranty statements) will not indicate five or more years.	

**ATTACHMENT 2
ARTICLE 2 COMMENTS**

Article 2 -- Chemicals of Concern Identification Process			
Section	Title	Comment	Proposed Text
§ 69502.2.(a)(1)	Chemicals of Concern Identification	HP supports using a list of lists to generate the Chemicals of Concern list because this approach relies on authoritative bodies to make determinations on substances and will be more harmonized with other jurisdictions. There is one concern with one of the sources, however. The CEPA PBiT list referenced in 69502.2 (a)(1)(H)) is not an authoritative list and will not be maintained over time. It was a very useful screening step that provided a one-time review of substances on Canada's DSL, however, the more appropriate authoritative list would be Schedule 1. Schedule 1 is maintained over time, is based on expert review, has been prioritized, and covers both existing and new substances used in commerce.	69502.2 (a)(1)(H)) Chemicals that are identified as Persistent, Bioaccumulative, and Inherently Toxic Substances to the environment by in the Canadian Environmental Protection Act Environmental Registry Domestic Substances List Schedule 1.
§ 69502.2.(b)(4)	Safer Alternative	HP suggest deleting Section 69502.2(b)(4) because the existence or not of a "safer alternative" should have no bearing on whether a chemical is identified as a COC. If DTSC determines a chemical has a hazard trait or environmental or toxicological endpoint that satisfies listing criteria, that chemical should be listed regardless of whether there are known safer alternatives. If a chemical does not exhibit a hazard trait or environmental or toxicological endpoint that satisfies listing criteria, that chemical should not be listed regardless of whether there are known safer alternatives.	Delete Section 69502.2(b)(4) in its entirety.

**ATTACHMENT 3
ARTICLE 3 COMMENTS**

Article 3 -- Chemicals of Concern and Consumer Product Prioritization Process			
Section	Title	Comment	Proposed Text
§§ 69503.2(b) and 69503.3(e)	Priority Products Prioritization Factors and Process to Evaluate Products Using the Prioritization Factors - Key Prioritization Factors	AB 1879 tasks DTSC with adopting “regulations to establish a process by which chemicals of concern in products, and their potential alternatives, are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern.” Health and Safety Code Section 25252(a) states specifically that the regulations adopted shall establish an identification and prioritization process that “includes, but is not limited to, <i>all</i> of the following considerations: (1) The volume of the chemical in commerce in this state. (2) The potential for exposure to the chemical in a consumer product. (3) Potential effects on sensitive subpopulations, including infants and children” (emphasis added). The proposed regulations at Section 69503.2 and 69503.3 set forth prioritization factors and processes to determine the priority products for which the AA process will be triggered. DTSC states that its intent of this section is to provide “responsible entities, stakeholders and interested parties predictability and certainty regarding the specific aspects DTSC will be evaluating to prioritize Chemicals of Concern in products to determine which products are of high priority and should be listed as Priority Products.” Initial Statement of Reasons at 89. For the process to have predictability and certainty, and to enable AB 1879’s clearly-stated objective to “reduce the level of hazard posed by a chemical of concern,” the Regulations’ key prioritization factors must focus initially with the three statutory considerations and demonstrate that <i>all</i> these have been adequately considered, and only then go on to other considerations. Demonstrating that the statutory criteria have been satisfied would include setting forth a clear delineation of how DTSC will determine how all three statutory criteria are satisfied and then how DTSC will weigh any other prioritization factors. With the current system, there is no weighting of factors and thus no discernible “process” by which anyone can apply the criteria in a manner that is reasonable and fair, resulting in a “process” that by its very nature is arbitrary and capricious. Focusing on the statutory criteria first and then considering the remaining criteria only when all statutory criteria are satisfied will increase predictability, improve the transparency of the prioritizing process for both chemicals and products, and make the program more workable for DTSC and affected companies.	
§ 69503.3(d)	Process to Evaluate Products Using the Prioritization Factors - Safer Alternatives	HP suggest deleting Section 69503.3(d) because it is inappropriate for the Department to make determinations about the potential existence of a “safer alternative,” that appears also to requires further determinations of whether a product is “functionally acceptable and technically and economically feasible” before listing a Priority Product. These types of determinations cannot be made by the Department without first obtaining input from affected stakeholders.	Delete Section 69503.3(d) in its entirety.
§ 69503.3(g)	Process to Evaluate Products Using the Prioritization Factors -- Initial Priority Product List(s)	HP supports the Department’s attempt to prioritize the CoCs as set forth in Section 69503.3(g), which will create a sub-list of COCs that the Department will use to select Priority Products until January 1, 2016. This subset of COCs provides all interested stakeholders with needed information regarding the focus and prioritization of the larger COC list and effectuates AB 1879’s intent to prioritize COCs and Priority Products. HP is concerned, however, that the Department will creating this sub-list but then plans to rely upon it for less than three years from when the program commences. Arguably, there is no need to create a sunset date after which the Department will not use this list. The Department has stated that it initially will be taking action on no more than five Priority Products so it can “gain experience and knowledge to refine implementation of these regulations.” To further this important goal, the Department should consider the benefits and utility of relying upon the sublist of COCs for at least seven years from the date the program becomes effective.	(g) Initial Priority Products List(s). Prior to January 1, 2020 2016, the Department may list a product as a Priority Product only if the product is being listed on the basis of one or more Chemical(s) of Concern in the product that meet both of the following criteria:
§ 69503.5(c)	Priority Products List	HP recommends that when AA Thresholds are set for particular COCs in Priority Products pursuant to Section 69503.5(c), the Department must define the preferred test method(s) and practical quantitation limits. In addition, HP recommends that when particular Priority Products are listed, the Department provides a level of product specificity required for notifications (<i>e.g.</i> , general application type, representative product, products by model, each product SKU). If there may be varying levels of specificity for different Priority Products, the Department may be required to develop new definitions setting forth the meaning of potentially different levels.	(c) The Department shall specify an alternatives analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product and will specify the preferred test method(s) and practical quantitation limits for determining the Threshold.

**ATTACHMENT 3
ARTICLE 3 COMMENTS**

Article 3 -- Chemicals of Concern and Consumer Product Prioritization Process			
Section	Title	Comment	Proposed Text
§ 69503.4. (a)(2)(B)2.-3	Highly Durable Products	The Department states that the provisions for “highly durable products” are intended to limit the components or homogeneous materials in the component subject to an analysis to ten or fewer per durable product every three years to provide manufacturers with adequate time to address the durability requirements of the product. Although well-intentioned to reduce concerns that a product could be subject to an unmanageable number of AAs simultaneously, the provisions for “highly durable products” are neither practical nor implementable. First, though the Department may think it is limiting these products to 10 AAs per product within a 3-year timeframe, this is still an unmanageable number of AAs within the time provided. In addition, life cycle work is time consuming and expensive. HP understands the Department's desire to distinguish between Priority Products types and provide some boundaries for how AAs will be conducted for complex products, but the definition provided does not accomplish the Department's goal because manufacturers do not generally “routinely prepare” information on anticipated useful life, as warranty periods do not indicate actual useful life. Since there is no real advantage being provided for this class of products, this section should be deleted, and all COC/Priority Product combinations should be governed by the same program and rules. In the alternative, HP suggests deleting the definition for highly durable products, reinstating the now-deleted definition for assembled product, and further restricting the number of AAs that could apply to a product within a three year period. At a minimum, the definition of “highly durable products” should be deleted from this Section and added to the Definition Section and the definition should delete the requirement that “Manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five (5) or more years.”	
§ 69503.4. (a)(2)(C)		As currently written, the deadlines for submission of Preliminary AA Reports may not be the same for all related responsible entities. To ensure a level playing field, if there are multiple AA submissions, the Department should state clearly in the Regulations that the deadline for submission of AA Reports will be the same for all responsible entities and that any extension granted for one responsible entity will apply for all responsible entities.	(C) The due date for submission of the Preliminary AA Report, required under article 5. The due date for the Preliminary AA Report shall be 180 days after the date the product is listed on the final Priority Products list, unless the Department specifies a shorter or longer period of time, which shall apply to all responsible entities for that Priority Product.
§ 69503.5.	Alternatives Analysis Threshold Exemption	HP understands the flexibility that DTSC is seeking to set appropriate thresholds based on the specific toxicity of a CoC at issue and the particular exposure scenarios of the Priority Product containing that CoC by developing individual “Alternatives Analysis Thresholds.” HP also believes that, pragmatically, the development of each AA Threshold will be very challenging and will consume enormous, potentially unnecessary, DTSC resources. Having a starting point (default) threshold for triggering AAs, which can be modified as necessary, may make the process for setting AA Thresholds less challenging. Defaults are used in well-developed regulatory systems around the world and provide needed guidance for companies trying to reduce concentrations and exposures. A default will also facilitate a more reasoned discussion about the potential impact of a particular CoC instead of triggering an automatic drive to the minimum detectable concentration, which will not be necessary in many cases. To achieve a default level that may be acceptable to a greater number of stakeholders, HP could support a default threshold of 100 ppm that can be adjusted higher or lower based on reliable information.	
§ 69503.6.	Alternatives Analysis Threshold Exemption Notification	AA Threshold Exemptions should be self-implementing and require no notice to the Department. If a responsible entity does not have the COC of interest above the AA Threshold in its product, it should not be penalized by requiring the preparation and submission of an Exemption Notification. By eliminating this Notification, DTSC would provide an incentive to industry to remove or reduce the concentration of a CoC at issue from its products as well as reduce DTSC's costs and obligations to implement this program. Although not related to this Notification provision, AB 1879 does task the Department in other contexts “to minimize costs and maximize benefits for the state's economy.” Eliminating the AA Threshold Exemption Notification is a simple means to reduce the Department's regulatory burden without compromising the integrity of the program.	Delete 69503.6 in its entirety.

**ATTACHMENT 4
ARTICLE 5 COMMENTS**

Article 5 -- Alternatives Analysis			
Section	Title	Comment	Proposed Text
§ 69505.	Guidance Materials	HP supports the Department's intent to make available on its website guidance materials to assist persons in performing AAs. HP recommends that DTSC include in its guidance materials structured forms as one way to help responsible entities meet the requirements of Article 5.	
§ 69505.1(c)(3)	Alternatives Analysis: General Provisions	Section 69505.1(c)(3) specifies the timeframes within which Preliminary and Final AA Reports will be submitted. This Section also references other Sections that state that the Department can specify a different due date and that the Department can approve an extension request. The Regulations thus provide a circumstance when there could be different deadlines for different entities performing AAs for the same CoC/Priority Product combination. This would result in business and competitive inequities that should not be permissible. Instead DTSC should ensure that all information is submitted to it at the same time to enable appropriate and consistent regulatory responses. DTSC should revise this Section to clarify that there will be only one deadline that will apply to all companies. The procedures for seeking extensions could be retained, but an extension granted for one company for a particular AA step would need to be extended to all entities subject to the same AA for the same COC/Priority Product.	(3) A responsible entity subject to the requirements of paragraph (2) shall prepare, sign, and submit to the Department AA Reports, meeting the requirements of section 69505.5, as follows: (A) Except as provided in subsection (d)(1), the all responsible entity(ies) shall submit the Preliminary AA Report(s) no later than 180 days after the date the product is listed on the final Priority Products list posted on the Department's website, unless the Department specifies a different due date for the product in the Priority Products list under section 69503.4(a)(2)(C), which shall apply to all responsible entities for that Priority Product. (B) Except as provided in subsection (d)(1), the all responsible entity(ies) shall submit the Final AA Report(s) no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, under section 69505.5(k)(1), and the Department approves, under section 69505.6(a)(3), a longer period of time, which will apply to all responsible entities preparing Preliminary AA Reports for the same Priority Product for which an extension is granted.
§ 69505.2.(b)(4)	Abridged AA Report	The Proposed Regulations provide that if no alternative is found for a CoC, an Abridged Report can be filed after Phase 1. The purpose seems to be that a "functionally acceptable alternative is not available or feasible," a responsible entity should not have to complete the cumbersome Phase 2 AA analysis. The Department should clarify what are the criteria for "not feasible" and "not available" so that entities do not avoid complete AAs unfairly. Also, the Department should issue a single regulatory response for each CoC/Priority Product combination, based on the aggregate finding of all AA reports, including AA Abridged Reports, not individual responses as requested by the responsible entities.	
§ 69505.2.(d)	Multiple Alternatives	This section requires that entities select a single alternative, and subsequently notify the Department if another alternative is used. This is a highly undesirable situation because OEMs use materials and components from different suppliers, and different suppliers may have different optimal solutions. The only criteria for eliminating an alternative from consideration should be evidence of significant burden shifting. Any less hazardous option that shows no significant burden shifting should be allowed as a potential replacement, which will allow the supply chain and market to resolve remaining issues. This approach encourages suppliers to find the most cost-effective and innovative solutions. Section (d) should be eliminated, and 69505.4 (c) should be modified to allow multiple alternatives to the CoC.	
§ 69505.3. (b) (3) (C)	Step 3 in Phase 1 AA	We support eliminating alternatives that pose greater or equal risk of adverse public health and/or environmental impacts. The guidance documents should address the question of what is considered an unacceptable alternative because there are many ways to balance different health and environmental impacts.	

**ATTACHMENT 4
ARTICLE 5 COMMENTS**

Article 5 -- Alternatives Analysis			
Section	Title	Comment	Proposed Text
§ 69505.3. (b) (4)	Step 4 in Phase 1 AA	As long as there are alternatives that can advance to Phase 2, any criteria should be valid for eliminating alternatives at this step. Such a provision will be helpful in cases where there are many potential alternatives (such as with flame retardants), and it is necessary to narrow the list of alternatives to a manageable number for Phase 2. This should be addressed in the Final Statement Of Reasons and this Section.	(4) Step 4, Consideration of Additional Information. As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified in this section. This may include consideration of the factors and information identified in section 69505.4. Any alternative may be eliminated from further consideration based on this additional information as long as the reason for its elimination is documented and there are alternatives remaining to be evaluated in Phase 2.
§ 69505.3. (b) (5)	Step 5: Work Plan for Phase 2	The intended content of the Work Plan is not clear. The Department should provide more specifics about the level of detail required for each Work Plan. For example, it would be helpful to clarify if it is intended to be merely a schedule, or if it must list activities and estimated milestone dates. These details should be added in the Final Statement Of Reasons and Section 69505.5.(k)(1)(A).	
§ 69505.4.	Step 1: Retaining CoC for Comparison	We support retaining the original CoC(s) as the baseline for all Phase 1 and Phase 2 comparisons.	
§ 69505.4.(a) (2)(C)	Economic impacts	We support the clarification that a complete economic evaluation need only be conducted if the responsible entity is attempting to justify continued use of a COC. This section should be clarified that there should not be a requirement to include an evaluation of economic impact in cases where: (1) there are multiple alternatives under consideration; (2) no alternative under consideration shows significant burden shifting; and (3) cost is not being used as a justification to continue to use a COC. Economic impact analyses, as described here, are extremely difficult to perform and add little to the Department's ability to select appropriate regulatory action, as long as the Department does not try to dictate the specific solution that responsible entities must use. Responsible entities will certainly bring in any relevant cost impacts to their decision-making.	
§ 69505.4.(b)(1-8)	Step 2 of Phase 2 AA	Items 1-8 should be deleted because they are too prescriptive. This level of detail would be more appropriate (and flexible) in guidance documents. The general idea of these criteria are also already addressed in 69505.4(a)(2).	Delete § 69505.4.(b)(1-8) in its entirety.
§ 69505.4.(c)	Selecting Alternatives	It should not be the goal of Phase 2 to identify the best, single alternative, but rather to identify unacceptable alternatives. The primary purpose of Phase 2 should be to identify any significant burden shifting that would be expected to occur if an alternative were widely adopted, and potentially to use that information as a basis for deciding that an alternative is unacceptable. Therefore, any alternatives that do not pose an equal or greater risk of adverse impacts should be considered acceptable. This section should be modified to reflect that a single solution is not required.	(c) Step 3, Alternative Selection Decision. The responsible entity shall select the alternative(s) that will replace or modify the Priority Product, unless the decision is to retain the existing Priority Product.
§ 69505.4.(d)	Consideration of Additional Information	This step should occur before the alternative(s) are selected. HP recommends switching the order between Sections (c) and (d).	
§ 69505.4.(e)	Identification of Next Steps	This section should be simplified such that the AA Final Report content requirements are all in one place (Section 69505.5.).	(e) Step 5, Identification of Next Steps. (1) The responsible entity shall prepare a Final AA report that contains all of the information required in 69505.5.
§ 69505.5. (d)(3-5)	Responsible Entity and Supply Chain Information	Items 3-5 are highly proprietary, difficult to collect, and of questionable value to evaluating an AA. They should be deleted.	Delete § 69505.5. (d)(3-5) in its entirety.

**ATTACHMENT 4
ARTICLE 5 COMMENTS**

Article 5 -- Alternatives Analysis			
Section	Title	Comment	Proposed Text
§ 69505.5. (j)(2)	Selected Alternatives in Final AA Report	This section should be modified to allow multiple alternatives to be found to be acceptable. As long as the alternatives do not pose an equal or greater risk of adverse impacts and there is no significant burden shifting, they should all should be considered acceptable. This section should be modified to reflect that a single solution is not required.	(2) The Final AA Report must identify and describe the alternative(s), if any, selected to replace or modify the Priority Product. The description of the selection decision must include an analysis that evaluates and compares the selected alternative(s) against the Priority Product and a detailed list and explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. The Final AA Report must also include all of the following: (A) The information specified in section 69505.4(a)(2)(B) for the selected alternative(s). If no alternative is selected, this information must be provided for each alternative considered.
§ 69505.5. (k)(1)	Work Plan for Phase 2	The intended content of the Work Plan is not clear. The Department should provide more specifics about the level of detail required for each Work Plan. For example, it would be helpful to clarify if is intended to be merely a schedule, or if it must list activities and estimated milestone dates. These details should be added in the Final Statement Of Reasons and Section 69505.5.(k)(1)(A).	
§ 69505.5. (k)(1)	Uniform Deadlines	The Department should state clearly in the Regulations that the deadline for submission of AA Reports will be the same for all responsible entities and that any extension granted for one responsible entity will apply for all responsible entities.	
§ 69505.5. (k)(2)	Implementation Plan	It is premature to ask for an implementation plan before a regulatory response has been determined by the Department. This section should be modified to allow for an entity to submit a proposed transition plan and to suggest regulatory responses, but not require them to do so.	(2) The Final AA Report may include: (A) A proposed implementation plan, with key milestones and dates, for implementing the selected alternative, if applicable, and identifying applicable federal, state, or local laws and steps that will be taken to ensure compliance with those laws. (B) Any regulatory response(s) that the responsible entity wishes to propose that would limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, any Chemical(s) of Concern that will be in the selected alternative or that is in the Priority Product if the decision resulting from the AA is to retain the Priority Product.
§ 69505.6.	Department Review and Determination for AA Reports	The Department must review each AA Report in order to meet the requirements of this section, so it is not clear that there is a significant benefit to having a certified assessor program. See HP's extended comments on Article 8 for more detail.	
§ 69505.6(a)(3)	Department Review and Determination for AA Reports	Section 69505.6(a)(3) specifies the timeframes within which Final AA Reports will be submitted. This Section also references other Sections that state that the Department can specify a different due date and that the Department can approve an extension request. The Regulations thus provide a circumstance when there could be different deadlines for different entities performing AAs for the same CoC/Priority Product combination. This would result in business and competitive inequities that should not be permissible. Instead DTSC should ensure that all information is submitted to it at the same time to enable appropriate and consistent regulatory responses. DTSC should revise this Section to clarify that there will be only one deadline that will apply to all companies. The procedures for seeking extensions could be retained, but an extension granted for one company for a particular AA step would need to be extended to all entities subject to the same AA for the same COC/Priority Product.	(3) The Department shall specify in a notice of compliance the date for submitting the Final AA Report. The Department shall specify a due date that is twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify more time for submission of the Final AA Report if it determines based on information in the Preliminary AA Report that more time is needed. The Department may not establish a due date for the Final AA Report that is more than twenty-four (24) months from the date the Department issues the notice of compliance for the Preliminary AA Report, except as provided in sections 69505.1(d) and 69505.5(k)(1)(C). Any due date established for a Final AA Report shall apply for all responsible entities submitting a Final AA Report for the same Priority Product.

**ATTACHMENT 5
ARTICLE 6 COMMENTS**

Article 6 -- Regulatory Responses			
Section	Title	Comment	Proposed Text
§ 69506(a)	Regulatory Response Selection Principles	As discussed in more detail in HP's October 11, 2012, letter comments, a deep flaw in these proposed Regulations is that DTSC is theoretically allowed to select different regulatory responses for different responsible entities. HP finds this possibility profoundly unfair and believes it creates a situation ripe for claims of impropriety by DTSC with regard to different treatment for different entities. Even the potential appearance of impropriety should be sufficient for DTSC to recognize that this must be rectified. DTSC states that the procedures set forth in proposed Section 69508.3 for the "Accreditation Body Designation Process" are "necessary to ensure that DTSC's actions are standardized and applied fairly." Initial Statement of Reasons at 196. DTSC also states that proposed Section 69507.6(f) provides that no DTSC staff who participated in making or reviewing the disputed decision may participate in the decision-making or review of decisions made under Section 69507.6 because that "is necessary to ensure that DTSC's review is fair and objective." If DTSC is concerned, as it should be, with ensuring that its procedures are standardized, fair, and objective, then DTSC should ensure the Regulations provide a level playing field by stating that all AAs for the same CoC will be reviewed by the Department at the same time, and that DTSC will issue a single public policy decision with the most appropriate regulatory response. For DTSC to conduct simultaneous reviews, it must also ensure that the deadlines for submission as the same, as discussed in HP's comments with regard to Section 69505.1(c)(3).	The Department shall identify and require implementation of regulatory responses applicable to all responsible entities required to perform an AA for a particular Priority Product that are designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.
§ 69506.9	Advancement of Green Chemistry and Green Engineering	Health and Safety Code Section 25253(b) states: "The regulations adopted pursuant to this section shall specify the range of regulatory responses that the department may take following the completion of the alternatives analysis, including, but not limited to, any of the following actions: ... (8) Imposing a requirement to fund green chemistry challenge grants where no feasible safer alternative exists." While not questioning DTSC's authority, when the criteria are satisfied (i.e., "where no feasible safer alternative exists"), to require a manufacturer to fund green chemistry challenge grants, HP finds no basis for DTSC to extend its authority to require manufacturers to initiate specific research and development (R&D) projects relating to safer alternatives for priority products. HP is not aware, for example, that EPA has ever required a company, without its consent, to conduct specific R&D research as part of TSCA Section 5 significant new use rules, TSCA Section 4 test rules, Section 4 enforceable consent agreements, FIFRA data call-ins, or supplemental environmental projects. DTSC's Initial Statement of Reasons provides no explanation or basis for this apparent increase in authority or scope. Moreover, an R&D project intended to develop a "feasible safer alternative" inherently will involve enormous confidential and trade secret concerns that will be impossible to address. With no authority from AB 1879 and concerns regarding the ability to implement such a requirement, HP believes that DTSC must delete the words "initiate a research and development project or" from Section 69506.9 and focus instead on funding challenge grants to accomplish these objectives. The regulatory text should likewise be more explicit with regard to when "no feasible safer alternative exists," a condition that must be met under AB 1879 before funding challenge grants is permissible.	The Department may require a manufacturer to initiate a research and development project or fund a challenge grant pertinent to the Priority Product for which there is no feasible safer alternative that uses green chemistry and/or green engineering principles to do one or more of the following: (a) Design a safer alternative to the Priority Product; (b) Improve the performance of a safer alternative to the Priority Product; (c) Decrease the cost of the safer alternative to the Priority Product; and/or (d) Increase the market penetration of a safer alternative to the Priority Product

**ATTACHMENT 6
ARTICLE 8 COMMENTS**

Article 8 -- Accreditation Bodies and Certified Assessors			
Section	Title	Comment	Proposed Text
Article 8	Accreditation Bodies and Certified Assessors	As discussed in more detail in HP's October 11, 2012, letter comments, HP strongly urges DTSC to delete the accreditation bodies and certified assessors procedures and thus the entire Section 69508 should be deleted.	Delete Section 69508 in its entirety.
§ 69508.	Qualifications and Certification for Assessors	If DTSC insists on retaining a certified assessors program, HP urges DTSC to make significant changes to who would qualify as a certified assessor. Companies should be using their best, most knowledgeable staff to conduct these evaluations, even if those people are not in California or do not maintain certified status. As stated elsewhere in these comments, if the Regulations are implemented in a way that reduces the need for multiple AA assessments on any particular CoC/product combination, the need will be reduced for highly skilled subject matter experts to obtain and maintain a certification. The requirements for certification should be drastically simplified to allow experts in this subject matter, without regard to particular educational backgrounds, to be certified in an efficient manner. Requiring potential assessors to successfully complete an approved challenge test developed by the accreditation body will provide more than enough evidence of the competency of the assessor.	Delete Section 69508(a) in its entirety; modify Section 69508(b) so that certification can be accomplished through a computer-based training module with an approved challenge test developed by an accreditation body; clarify in Section 69508(c) that the challenge test part of the computer-based training can be completed online.
§ 69508.1	Qualifications for Accreditation Bodies	Section 69508.1 should be modified so the requirements are reduced and accreditation bodies are not limited to California universities.	

**ATTACHMENT 7
ARTICLE 10 COMMENTS**

Article 10 -- Trade Secret Protection			
Section	Title	Comment	Proposed Text
§69510.(a)(6)-(7)	Assertion of a Claim of Trade Secret Protection	HP is concerned that two of the substantiation questions are not consistent with substantiations already required on the federal and state level by asking for specific information on “economic” values that are difficult if not impossible to quantify. Specifically, the proposed Regulations ask for an explanation of the “estimated value of the information to the person and the person’s competitors” and the “estimated amount of effort and/or money expended by the person in developing the information.” See Section 69510(a)(6)-(7). Determining a specific value, even as an estimate, is a potentially enormous undertaking considering all the R&D, product testing, market development, technical support, and other related activities involved. In many cases, the information’s value will not decline over time, making an estimated value even more difficult to compute if it must be presented as a present-day value. Any value provided to DTSC will be equally difficult to evaluate, as any particular number could have widely different importance to different companies depending on several factors, including the company’s size, the size of a particular market, the size of a company’s market share in a particular market, and so forth. HP urges DTSC to follow models established on the federal and state level that ask substantiation questions focusing on the efforts a company has taken to keep the information confidential and the information a company has that such information has not been released publicly. With regard to the “economic” or “trade” value, HP believes that the proposed questions at, for example, Section 69510(a)(8) (asking how the information could be used or duplicated by competitors) and Section 69510(a)(10) (asking for a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed) speak for themselves as to harmful effects of a company’s competitive and economic position.	Delete Sections 69510(a)(6)-(7) in their entirety.

ATTACHMENT 8

HP'S ALTERNATIVE ASSESSMENT PROGRAM EXAMPLE

Reducing Risk by Reducing Hazard – Use of Chemical Hazard Screening as the First Step in the Assessment Process

Hans Wendschlag^{*1}, Cory Robertson², Helen Holder³, Curtis Wray⁴

¹Hewlett-Packard Co., Stockholm, Sweden

²Hewlett-Packard Co., Boise, USA

³Hewlett-Packard Co., Palo Alto, USA

⁴Hewlett-Packard Co., Fort Collins, USA

* Corresponding Author, hans.wendschlag@hp.com, +46 8 524 94906

Abstract

With the introduction of materials specific legislation, such as RoHS in 2003, the pace of change of materials in the electronics industry has seen a dramatic increase. Changing materials is costly, and an important business need is the development of a process to select alternatives that will not need to be substituted in the future. To guard against multiple substitutions, the alternatives selected need to have lower impacts on human health and the environment. According to the principles of green chemistry the most efficient way to reduce overall risk is to use less hazardous materials in product design. To guard against regrettable substitution, and future restriction, an alternatives assessment process including chemical hazard assessment as the first step in the process is described. Example applications of the alternatives assessment process are introduced.

1 Introduction

The electronics industry faces increasing regulatory and consumer pressure to remove substances of concern from electronic and electrical products. The pace of change in the materials electronics has increased substantially since the adoption of RoHS in February 2003. EU *Directive 2002/95/EC on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment* (commonly referred to as RoHS) was part of an effort to reduce the inherent toxicity of electronics waste and to mitigate the effects of its disposal. The RoHS restrictions on the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers created an instant need for alternative materials.

In order to make an informed decision data on the alternatives is needed. The RoHS restricted substances had been used in electronics for many years and were well studied. Many were concerned that the alternative substances had not been sufficiently evaluated to ensure that they would have less impact on human health and the environment. Assessments showed mixed results for the alternatives in comparison with the original materials [1] [2].

The EU directive does not indicate what the alternatives should be so manufacturers and their suppliers developed their own criteria for selecting alternatives. For some suppliers this is an informal process with cost being the primary criteria, other suppliers have a more formal process with multiple criteria. From a

business perspective, it is undesirable to face future restrictions for the same application due to a poor choice of replacement materials. Changing materials only after careful consideration of the alternatives will help avoid unintended consequences and prevent regrettable substitutions [3]. Uninformed decisions may cause manufacturers to change materials multiple times, incurring the cost of transition each time [4]. Chemical substitutions can be costly, and the required changes can be disruptive to product releases. In light of the trend towards more chemical regulation and substance restriction, there is a growing risk of multiple substitutions unless potential replacement technologies are properly assessed against environmental and human health criteria in advance of their widespread adoption.

A comprehensive approach accounting for the many variables of material selection, including environmental and human health concerns, is needed. The emerging field of green chemistry addresses many of the core issues of sustainability at the design phase, where the most efficient change is achieved.

2 Green Chemistry

The term green chemistry shares similar concepts with other programs such as benign by design, pollution prevention and design for the environment. The definition of green chemistry describes all of these concepts, "Green chemistry is the utilization of a set of principles that reduces or eliminates the use or genera-

tion of hazardous substances in the design, manufacture and application of chemical products” [5].

Risk is a function of hazard and exposure. Traditional approaches to reducing risk have focused on reducing exposure using techniques such as personal protective equipment or encapsulation of toxic materials with non-toxic coatings for instance. Many of the large chemical companies spend as much on environmental health and safety to protect their workers from hazardous chemicals as they do on research and development [5]. The green chemistry approach focuses on reducing risk by using materials that are inherently less hazardous.

3 The GreenScreen™ for Safer Chemicals

Recognizing the need for a better way to evaluate whether alternatives have a lower overall adverse impact to human health and the environment, an integrated assessment approach was developed for analyzing potential replacements. This integrated approach incorporates a comparative chemical hazard screening step based on a tool called the GreenScreen™ for Safer Chemicals, a framework launched in 2007 by the non-governmental organization Clean Production Action [6].

The GreenScreen™ is an open-source, comparative chemical hazard assessment tool. The tool provides a clear and transparent decision logic that assesses 17 globally harmonized endpoints for environmental fate, human health, and environmental toxicity, and then generates benchmark scores ranging from the most to the least hazardous. The hazard endpoints are shown in Figure 1.

Environmental Fate

- Persistence
- Bioaccumulation

Environmental Health

- Acute Aquatic Toxicity
- Chronic Aquatic Toxicity

Human Health Group I

- Carcinogenicity
- Mutagenicity and Genotoxicity
- Reproductive Toxicity
- Developmental Toxicity
- Endocrine Activity

Human Health Group II

- Acute Mammalian Toxicity
- Systemic Toxicity and Organ Effects
- Neurotoxicity
- Respiratory Sensitization
- Skin Irritation
- Eye Irritation

Physical Hazards

- Reactivity
- Flammability

Figure 1: GreenScreen™ version 1.2 hazard endpoints and groups

An important attribute of the GreenScreen™ is the alignment with the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) and with the U.S. EPA Design for Environment (DfE) program’s chemical alternatives assessment approach [4]. By aligning with these programs the assessments are more likely to identify chemicals that may be regulated in the future.

Another important feature of the GreenScreen™ is the simple 1 to 4 benchmark score. The GreenScreen defines four benchmark levels for substances:

Benchmark 1 –“Avoid – Chemical of High Concern”

Benchmark 2 –“Use but Search for Safer Substitutes”

Benchmark 3 –“Use but Still Opportunity for Improvement”

Benchmark 4 –“Prefer – Safer Chemical”

Once an expert assessor evaluates a group of chemicals, the results can easily be translated into procurement guidance for people without toxicology or chemistry backgrounds. The simple integer scoring system streamlines the decision making process putting the results in the hands of decision makers.

Hazard assessments are significantly faster and easier to complete than life cycle assessments or risk assessments because hazard endpoints are well-defined and are based on directly observable intrinsic traits or the behavior of a substance. Also, hazard data are generally available now that new EU chemical regulations require more disclosure of test data (REACH) [7]. The GreenScreen™ is not a replacement for risk assessment or life cycle assessment but it is very effective when used early in the product design process.

4 Integrated Alternatives Assessment Protocol (IAAP)

In order to maximize resources and utilize the strengths of the GreenScreen™, life cycle assessment and risk assessment, HP uses an integrated alternatives assessment protocol (IAAP). The GreenScreen™ alone does not address the full range of life cycle and exposure impacts and the IAAP provides a path to address these issues before final material selection. The IAAP combines the strengths of each assessment tool and allows each tool to be used as intended and at the appropriate time in the product design process.

Figure 2 shows the IAAP flow chart. The first step, identify substances of concern, may result from re-

striction of a chemical through regulation or by market pressure or scientific findings even before regulation. Once a target substance has been identified it is important to characterize the end use and function of the material, flame retardant alternatives must provide the same level of fire safety for instance. Step three is identify potential alternatives. This step requires working closely with suppliers to identify materials that could meet the environmental, regulatory and quality requirements. It is important to include many options at this point and not screen out too many options in order to promote innovative solutions including designing out the substance or function.

The fourth step introduces the first screening step, assess chemical hazards, and the GreenScreen™ is used along with R-phrases and restricted substance list (RSL) screening. It is important to assess the chemical hazard first to screen out alternatives that do not have lower impact on human health and the environment. Alternatives that fail to meet this requirement are placed in the deselected options but may be reconsidered if no viable technical solutions are found in step five.

The fifth step in the IAAP is to assess the technical and economic performance of the alternatives. The alternatives must provide equivalent technical performance. Some products may have specific requirements that must be met while the necessary performance requirements may need to be developed for other products, adding an additional challenge. Determining the right performance requirements is a critical step and gives suppliers a target to find the most cost-

effective solutions. The exact same performance as the original material may or may not be possible and it is important to understand the actual technical performance needed for the specific application.

Application of life cycle thinking and exposure considerations are considered in step six. A broader range of impacts to human health and the environment are taken into consideration such as global warming, end-of-life disposition and worker exposure. This consideration may be very brief or may trigger exposure studies taking many months to complete depending on the function and alternatives being considered. The TURI Five Chemicals Alternatives Assessment Study provides a good example of life cycle thinking [8].

Finally, in step seven, the alternatives are approved for use in products. The goal of the process is not to find a single optimum alternative but rather to find many acceptable alternatives. A range of acceptable alternatives provides suppliers with flexibility to choose materials that meet the needs of the application. In some instances the list of approved alternatives is documented and becomes a “white list” that can be used to identify the preferred alternatives.

5 Alternatives Assessment Projects

Alternatives assessment has been successful in improving materials selection during product development at Hewlett-Packard using multiple approaches. Alternatives assessment projects range from simple “white lists” to application of the IAAP described pre-

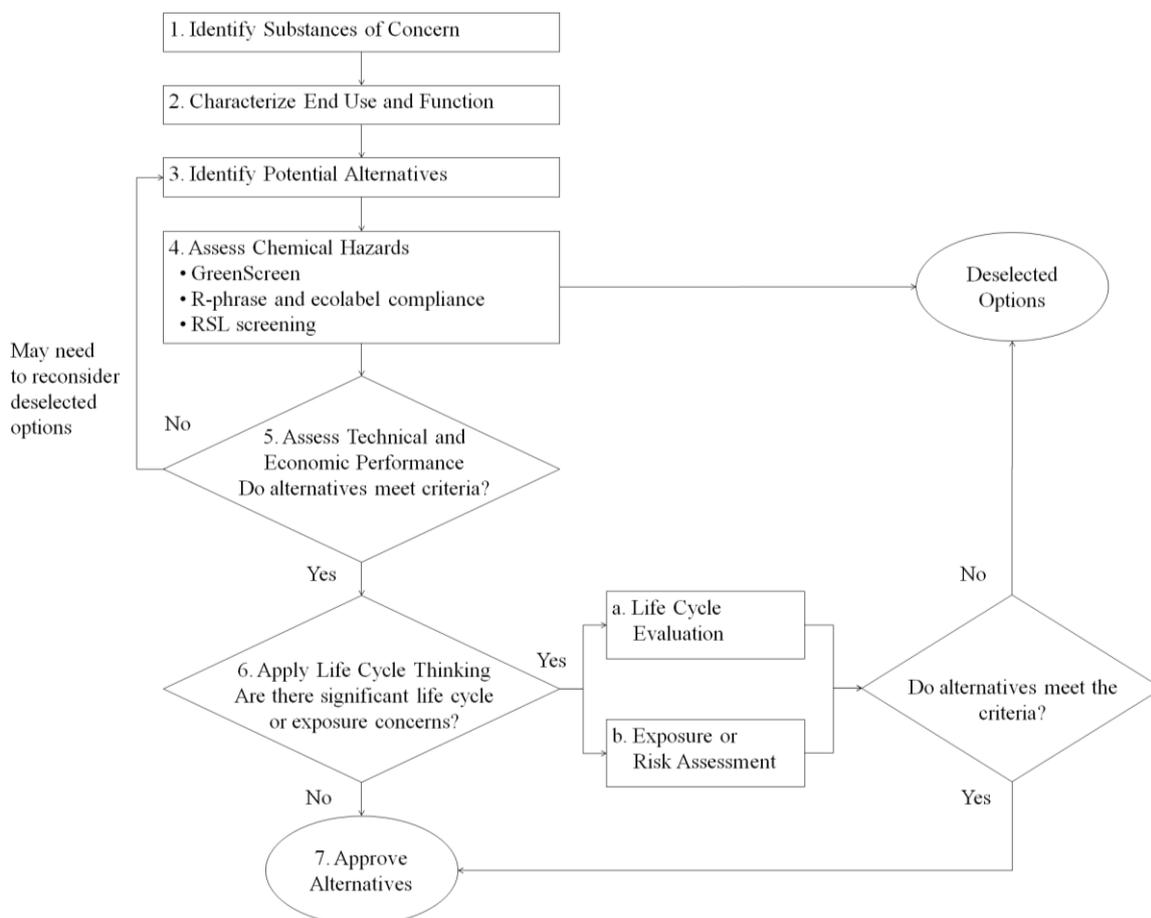


Figure 2. Integrated alternatives assessment protocol (IAAP) for evaluating replacements for restricted substances

viously. Several projects are described below.

5.1 Flame Retardant and Plasticizer White Lists

The earliest applications of alternatives assessment included the application of the GreenScreen™ to a class of materials to identify the preferred alternatives. Flame retardants and plasticizers were the first two classes of materials assessed with the GreenScreen™. The alternatives were classified into groups based on their benchmark score of 1, 2, 3 or 4. The list can then be used by product designers to quickly associate chemical hazard with a particular alternative.

Green Screen Assessments of Similar Function Chemical			
Common Name	CAS #	Full Name	Benchmark
Preferred			
Design	none	Design material out, dematerialize	4
Substance 0	#####-##-#	Chemical name	4
Use but still opportunity for improvement			
Substance 1	#####-##-#	Chemical name	3
Substance 2	#####-##-#	Chemical name	3
Use but search for alternatives			
Substance 3	#####-##-#	Chemical name	2
Substance 4	#####-##-#	Chemical name	2
Substance 5	#####-##-#	Chemical name	2
Substance 6	#####-##-#	Chemical name	2
DO NOT USE			
Substance 7	#####-##-#	Chemical name	1
Substance 8	#####-##-#	Chemical name	1
Substance 9	#####-##-#	Chemical name	1
Substance 10	#####-##-#	Chemical name	1
Substance 11	#####-##-#	Chemical name	1
Substance 12	#####-##-#	Chemical name	1

Figure 3: Material Class GreenScreen™ Summary

5.2 PVC-Free Power Cord Project

PVC is being phased out of many products throughout the electronics industry. In order to prevent regrettable substitution, alternatives assessment is a requirement for approval of alternatives to PVC power cords. The IAAP is applied to proposed alternatives and the approved alternatives are placed on an approved materials list. Cable manufacturers can then select materials from this list to construct power cords.

In order to validate the GreenScreen™ assessments performed by the suppliers or a third party, the formulations of the resins were revealed to HP under a confidentiality agreement. Some materials were deselected based on the GreenScreen™ results but a number of materials progressed to regulatory testing and have been approved for use. Resin suppliers attended mandatory training on the GreenScreen™ tool at the HP Fort Collins site in 2010.

Finished power cords were subjected to performance tests and compared to PVC cords as part of IAAP process. The technical requirements, including fire retardancy, were also an important part of the process

as the fire safety could not be compromised. Exposure assessments were a consideration in some formulations but for the most part the PVC and alternative cords would be used in the same way and the exposure potential for both is the same. Life cycle thinking was an important consideration, especially at end-of-life due to informal recycling and low temperature incineration.

5.3 Cleaners

HP is also applying alternative assessment protocol to spot cleaners that are used in the printed circuit board manufacturing process. Cleaners provide a unique case for alternatives assessment in electronics because these chemicals are used primarily in the manufacturing process and are not found in the finished product. Often exposure controls on the manufacturing line are present to reduce risk from cleaning chemicals; nevertheless, exposure controls can fail or may not be sufficient. Furthermore, cleaners used for repair and rework during electronics manufacturing are sometimes less controlled. Often this type of cleaning is done by hand using aerosol application; spot cleaning may also be done by a technician during a field repair. Recent news reports of poisoning from exposure to the cleaning chemicals at manufacturing plants underscore the need to decrease the inherent hazards of cleaners [9].

When we apply the IAAP to common cleaner formulations, many are easily deselected because they are known carcinogens or neurotoxicants. Once these chemicals are precluded, cleaner formulations can be chosen that minimize the hazard for manufacturing workers. Before these less hazardous formulations are adopted, they must meet technical performance criteria. Currently HP is working with cleaner formulators to develop effective cleaners that meet our hazard criteria.

The application of chemical hazard assessment to cleaners has highlighted some shortcomings of our current approach. We must determine a way to adequately assess mixtures of chemicals. For example, the hazard of some cleaner chemicals can be synergistic which must be taken into account during initial assessment [10]. In this case a chemical that may be acceptable by itself may be unacceptable when present with synergists. Conversely, small amounts of hazardous (GreenScreen™ Benchmark 1) chemicals may be needed to accomplish a particular application. We must determine if there are levels of chemicals that are acceptable to meet performance criteria. This decision can only be made once a thorough alternatives assessment is completed.

5.4 Fluxes

HP is in the initial stages of implementing an alternatives assessment program for solder paste and fluxes. These materials involve potential hazards during manufacturing and at the end-of-life of electronic products. Many flux formulations involve some sort of solvent vehicle and we want to minimize the hazard of these chemicals. Also, many flux residues, like PVC, are concerns due to their halogen content. When electronics are subjected to informal recycling (i.e. open pit burning), the presence of halogens can lead to hazardous byproducts.

6 Conclusions

The GreenScreen™ uses the principles of green chemistry to provide an important piece of information to product manufacturers, namely a simple benchmark score characterizing chemical hazard in a format that anyone understands. Chemical classification activities today provide a lot of information about chemicals in the marketplace but stop short of ranking chemicals based on their intrinsic hazard. The GreenScreen™ can provide this missing piece of information that can then be used by decision makers without toxicology background to make meaningful comparisons between material alternatives.

The GreenScreen™ has been used effectively in multiple projects within HP for several years. As a next step HP has been working with Clean Production Action and various ecolabel organizations to incorporate the GreenScreen™ as the materials requirement. Ecolabels such as TCO, Nordic Swan, Blue Angel and EPEAT, among others, currently depend on risk phrases and hazard statements for materials requirements which has several drawbacks. Using risk phrases rewards lack of data, if there is no data no risk phrase is assigned. Targeting risk phrases in a certain area of concern may neglect other areas of concern resulting in regrettable substitution. The GreenScreen™ has minimum data requirements and takes a more comprehensive approach assessing both environmental and human health concerns.

Furthermore, the scoring system allows manufacturers, and potentially ecolabel organizations, to effectively communicate materials goals to suppliers. By requiring a minimum GreenScreen™ benchmark rating, manufacturers can influence materials formulations at the most basic level. In addition, chemical suppliers could promote high benchmark solutions to product manufacturers. By promoting the use of benign materials up the supply chain where formulation decisions are made, the GreenScreen™ drives change where it is most effective: at the molecular level.

7 Literature

- [1] C.A. Ascencio, J.J. Madsen, "LCA comparison of alternative soldering techniques," PRÉ Consultants bv, 2005.
- [2] J. R. Geibig, "Solders in Electronics: A Life-Cycle Assessment," EPA 744-R-05-001, 2005.
- [3] R. D. McFadden, "The business case for transitioning to safer chemicals," *New Solutions* 21, no. 3:403-416, 2011.
- [4] E. T. Lavoie, G. Heine, H. Holder, M. S. Rossi, R. E. Lee, E. A. Conner, M. A. Vrabel, D. M. Difiore and C. L. Davies. "Chemical alternatives assessment: Enabling substitution to safer chemicals." *Environmental Science and Technology* 44(24): 9244-9249, 2010.
- [5] P. T. Anastas and J. C. Warner. "Green chemistry: Theory and practice," New York: Oxford University Press Inc., 1998, p. 11.
- [6] Clean Production Action, "GreenScreen™ for Safer Chemicals," [Online] Available: <http://www.cleanproduction.org/greenscreen.php>
- [7] "EC Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals" (REACH), No 1907/2006, 2007.
- [8] M. Ellenbecker, "Five Chemicals Alternatives Assessment Study," Toxics Use Reduction Institute, University of Massachusetts, Lowell, 2006.
- [9] D. Barboza, "Workers sickened at Apple supplier in China," [Online] Available: www.nytimes.com/2011/02/23/technology/23apple.html
- [10] O. Ladefoged, U. Hass and L. Simonsen, "Neurophysiological and behavioural effects of combined exposure to 2,5-hexanedione and acetone or ethanol in rats," *Pharmacol. Toxicol.* 65:372-375, 1989.

GCREgs@DTSC

From: GCREgs@DTSC
Sent: Tuesday, September 04, 2012 8:12 AM
To: hayley.hong@fiti.re.kr
Subject: FW: Question about proposed Green chemistry regulations

Thank you for your interest in the Safer Consumer Products regulations (file number Z-2012-0717-04). Your comments/inquiries are noted and in accordance with the Administrative Procedure Act (APA) process for adopting regulations, the Department of Toxic Substances Control will respond to your comments/inquiries in the Final Statement of Reasons for this rulemaking.

As a reminder, the Public Hearing will be held on September 10, 2012 and written comments must be submitted by 5:00 pm on September 11, 2012, in order to be considered for this proposed rulemaking. For additional information, please refer to: <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm>

From: Hayley Hong(홍희숙) [hayley.hong@fiti.re.kr]
Sent: Wednesday, August 29, 2012 10:50 PM
To: Regulatory Assistance Office@DTSC
Subject: Question about proposed Green chemistry regulations

Hello
I'm Hayley Hong from Korea.

I would like to know about the proposed green chemistry regulations.
I didn't understand that what "**priority products for which an alternative is not selected**" mean in safer consumer products summary of proposed regulation dated on July 17, 2012..
The priority products means not yet selected alternative or something different mean.

And in the graphics of overview for the safer consumer products regulations on your site,

Priority products requiring : Alternative analyses
Regulatory response(s) for selected alternative and/or priority product

Could you tell me what regulatory response(s) for priority product includes?

I'm looking forward to your reply.
Thank you

Best Regards- Hayley Hong

■■■
■■■ ■■■
■■■ ■■■

NOTICE IS HEREBY GIVEN that the Department of Toxic Substances Control is extending the 45-day public comment period for the Safer Consumer Product proposed regulations, which was published in the California Regulatory Notice Register (Z-2012-0717-04) on July 27, 2012.

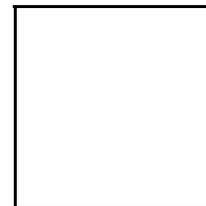
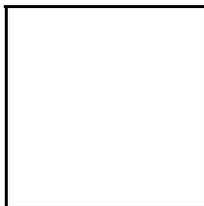
In response to numerous requests to extend the comment period due to the length and complexity of this rulemaking, the public comment period will now close at 5 p.m. on **October 11, 2012**.

The public hearing will proceed as initially scheduled on **September 10, 2012**.

Please direct any inquiries concerning this notice to:

Krycia Von Burg
Regulations Coordinator
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806
Tel: (916) 324-2810
Fax: (916) 324-1808
Email: gcregs@dtsc.ca.gov

[Forward this email](#)



This email was sent to pratikchhaporla@yahoo.com by gcregs@dtsc.ca.gov | [Update Profile/Email Address](#) | Instant removal with [SafeUnsubscribe™](#) | [Privacy Policy](#).
Department of Toxic Substances Control | P O Box 806 | Sacramento | CA | 95812-0806

▪

Valued Quality. Delivered.

Confidentiality Notice: This e-mail may contain confidential or privileged information, if you are not the intended recipient, or the person responsible for delivering the message to the intended recipient, then please notify us by return e-mail immediately. Should you have received this e-mail in error then you should not copy this for any purpose nor disclose its contents to any other person. <http://www.intertek.com>

Intertek Group plc is registered in England No.: 4267576 Registered Office: 25 Savile Row, London W1S 2ES

From: Bob Douthitt <BDouthitt@ci.el-centro.ca.us>
Sent: Thursday, October 11, 2012 2:25 PM
To: GCREgs@DTSC
Subject: Comments on Draft Regulations for Safer Consumer Product Alternatives

Importance: High

Dear Director Raphael:

The Imperial Valley Resource Management Agency has long been a supporter of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,

Bob Douthitt
IVRMA Manager
300 S Imperial Avenue, Suite 11
El Centro, CA 92243
Office 760-337-4589
FAX 760-337-3184
Cell 760-562-0123

*Please consider your environmental responsibility.
Before printing this e-mail message, ask yourself whether you really need a hard copy*



Independent Cosmetic Manufacturers & Distributors
21925 Field Parkway, Suite 205
Deer Park, IL 60010
Tel: 847-991-4499
1-800-334-2623
Fax: 847-991-8161
www.icmad.org

October 11, 2012

Via Electronic Mail

Kryisia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

gcregs@dtsc.ca.gov

Re: Comments on Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

The Independent Cosmetic Manufacturers and Distributors Association is commonly referred to as ICMAD. ICMAD is a non-profit trade association that was founded more than 40 years ago to educate and provide programs and services designed to assist the small to mid-sized creative, innovative cosmetic companies and to help them succeed in the rapidly changing, highly competitive cosmetics and personal care industries. ICMAD currently has over 650 small to medium size company members in the cosmetics and personal care industry, approximately 200 hundred of these companies are located in California.

While we recognize the consideration that the Department of Toxic Substance Control has given to the impact that these regulations will have on small business, this consideration does not replace the requirement for a complete analysis of the impact that these regulations will have on small business. We believe it is imperative that such an analysis be conducted before these regulations are finally adopted. An impact analysis when conducted will show that these regulations will have a significant and negative impact on small business. One indisputable reason for this is the high cost of obtaining the regulatory expertise necessary to assist these small businesses in compliance with these proposed regulations, a fact which the Department has recognized. Additionally the disparate impact that these regulations will have on small business, as opposed to larger businesses, will not be addressed by the Department's Alternative Analysis Guidance.

Beyond the forgoing we support the comments which have already been submitted to the Department regarding the lack of clarity in the Preemption provisions of these proposed regulations and the regulatory duplication that these regulations present with many long standing extensive Federal Regulatory programs. We also support the comments that have been made regarding the deletion of several of the lists adopted in the Regulations for the identification of Chemicals of Concern. Many of the included lists were not developed for the purpose for which they are now being used. We support the comments made regarding the criteria and process of selecting the Chemicals of Concern and the Priority Products of Concern. We further support the

comments regarding the need to address potential antitrust considerations to facilitate the formation of consortiums for Alternative Analysis process. We also support the development of meaningful concentration levels for Chemicals of Concern and limitations on selection to those chemicals for which there is conclusive and direct scientific evidence of significant risk. We also support the comments submitted regarding the need for greater Trade Secret protection in the Alternative Analysis.

Sincerely,

A handwritten signature in black ink that reads "Pamela Jo Busiek". The signature is written in a cursive style with a large initial 'P' and 'B'.

Pamela Busiek
President and CEO
ICMAD



Donna Maria Coles Johnson
Founder & CEO
6121 Pumpnickel Lane
Monroe, NC 28110

Tel 704-291-7280
www.IndieBeautyNetwork.com
IndieBusiness@gmail.com

October 11, 2012

Via Facsimile - 916-324-2810

Kryisia von Burg, Regulations Coordinator
Regulations Section - Department of Toxic Control Substances
PO Box 806
Sacramento, CA 95812-0806

Re: Comments Regarding Proposed Safer Consumer Product Regulations

Ms. Kryisia,

My name is Donna Maria Coles Johnson. I am the founder and president of the Indie Beauty Network (IBN), a nationwide trade organization serving small and independent soap and cosmetics manufacturers. IBN maintains a dues paying membership of over 900 small business owners, and a larger community of nearly 8,000 businesses, including retailers, consultants, packaging and suppliers and more. Thousands of our members and subscribers make and sell cosmetics in the State of California.

On behalf of IBN, I hereby submit these comments regarding the proposed safer consumer product regulations. IBN's members are strong advocates of consumer safety. However, we are concerned that the proposed regulations are not carefully tailored to minimize risk, and that they will unnecessarily burden companies that cannot absorb regulations that are not truly needed to protect consumers.

It is my understanding that the "chemicals of concern" and "priority products" have been or will be identified without specific input from small businesses. It is also my understanding that no analysis of the impact of the proposed regulations on small companies has been conducted.

So very many of the very small cosmetics companies in the State of California are owned by women, most of whom have grown their businesses "from scratch," without loans or outside investors. The livelihoods of thousands of these companies will be affected by the proposed regulations, yet their particular interests have not been considered.

I respectfully request that you proceed with great caution as you address the possible imposition of regulations that will affect the interests of so many people whose unique financial interests have not been considered. Thank you for your time and consideration.

Very truly yours,

/s/ Donna Maria Coles Johnson

Donna Maria Coles Johnson

GCREgs@DTSC

From: Diane Ingalls <diane@actions-speak.com>
Sent: Sunday, October 07, 2012 2:07 AM
To: GCREgs@DTSC
Subject: We count on our government...

When companies can't regulate themselves, get greedy, steal and poison products, we must be able to count on our government agencies and safe consumer legislation such as (file number [Z-2012-0717-04](#)) to be correctly voted on for our protection.

Thank you for listening and voting in good conscience. Diane Ingalls, 



October 10, 2012

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

RE: Intel Comments on July 2012 California Chapter 55: Safer Consumer Products

Intel appreciates the opportunity to provide input on the proposed Safer Consumer Products Regulations and we look forward to working with Department of Toxic Substance Control (DTSC) as it strives to finalize rules that are practical, meaningful and legally defensible. Intel supports the comments submitted by ITI, TechAmerica, CEA and SIA on behalf of the high-tech electronics industry and provides the following additional comments. These recommendations are aimed at ensuring that both DTSC and industry resources are focused on those uses of chemicals in consumer products that are of most concern to the citizens and environment of California.

Intel believes that technological advancement and environmental sustainability should go hand in hand. This philosophy is evident from our energy-efficient products to the industry initiatives we shape, and the way we responsibly manage our operations. We strive to minimize the environmental impact of our products at all phases in their product lifecycle: development, production, use, and ultimate disposal. To do so, we often develop solutions in collaboration with others. For example, over the last decade, we've worked with suppliers and customers, and participated in several industry consortia, in efforts to eliminate lead and halogenated flame-retardants from our products. Our experience with these efforts has helped to inform our comments below.

1. Inclusion of "Homogenous Material" Definition is Not Practical

While we support DTSC's objective in the proposed regulations to focus on a specific use of a chemical of concern within the product vs. the entire product, the inclusion of the term "homogenous material" is problematic from an enforcement and practical implementation standpoint. We urge DTSC to remove the term "homogenous material" from the proposed rule and adopt an alternative approach to meet the intent of focusing the alternatives assessment on a very specific use of a chemical of concern in a product.

The "homogenous material" definition is based on the European Union Restriction of Hazardous Substance (RoHS) Directive definition aimed at restricting six specific substances in electronic equipment. This definition is not readily scalable to the intent nor to the scope of CA Safer Consumer Products regulation.

For example, the first part of the definition "one material of uniform composition throughout" is a limited definition that does not apply to many complex materials that are

Intel Corporation
5000 W Chandler Blvd
Chandler, AZ 85226

used in consumer products today. This means that the second part of the definition, "combination of materials that cannot be disjointed or separated into different materials by mechanical actions..." will be a key part of definition that DTSC will have to demonstrate when listing a Priority Product use as a "homogenous material".

The EU RoHS Directive has been in effect for over six years. The semiconductor industry experience with the "homogenous material" definition in the Directive, has shown that there are many different interpretations on what can be considered to be "disjointed into different materials using mechanical actions". In practice, these differences mean that it is extremely difficult to enforce (for agencies) and to fully demonstrate compliance (for companies) to this definition.

For example, the EU Commission Frequently Asked Questions (FAQ) on the RoHS Directive indicated that an integrated component (IC) could be mechanically disjointed into the various homogenous materials. However, in practice, testing at the assembled IC component level is virtually impractical as the materials cannot be isolated from each other without cross contamination of the samples collected. In addition, even if it was possible to separate these materials from each other without any cross-contamination, the number of samples of ICs necessary to mechanically disjoint a sufficient quantity of the "homogenous materials" for analytical testing would be in the 100s or 1,000s of units due to the small amount of the materials used within the components, making compliance verification of any specific unit cost prohibitive and virtually impossible.

In addition, we are concerned that DTSC already uses term "homogenous material" in their Title 22 Section § 66260.202 regulations (aka "California RoHS") which is based on the EU RoHS definition. The electronic industry has been applying the same interpretation to both CA and EU "RoHS" regulations. Having potentially different interpretations of a key term such as "homogenous material" between CA RoHS and EU RoHS will be very confusing and problematic for the electronic industry. However, having potentially different interpretations between two CA Regulations such as the CA Safer Consumer Products and CA RoHS for the same term could be even more problematic for DTSC.

We understand that it is DTSC's intent to regulate, for example, steel belts within an automobile tire, rather than the entire tire, and that the homogenous material definition was included to address this intent. While the steel belts may be mechanically disjointable in an automobile tire example, this is clearly not the case for semiconductor ICs. We greatly appreciate DTSC's stated intent is not to regulate the different materials, for example, within a semiconductor integrated circuit (IC), under the homogenous material definition proposed due to the reasons stated above. But we remain concerned that the same practical implementation issues experienced in the electronics sector would also be experienced by other industry sectors if this problematic definition is included and applied as proposed. We urge DTSC to remove the term homogenous material from the rule and adopt the alternative approach recommended below to accomplish the same objective.

RECOMMENDATION:

We believe that the intent to focus on specific uses of Chemicals of Concern (COC) in Priority Products can be achieved without the problematic enforcement and implementation interpretation issues which are inherent in the homogenous material definition by the following:

- a) Modify the definition of component to include a reference to a uniquely identifiable material:

§ 69501.1.(21) "Component" means a uniquely identifiable part, piece, assembly, subassembly **or uniquely identifiable material within a single part, piece, assembly, subassembly** of a consumer product that:

- (A) Is required to complete or finish an item;
- (B) Performs a distinctive and necessary function in the operation of a system; or
- (C) Is intended to be included as a part of a finished item.

b) Remove the Homogenous Material Definition, § 69501.1 (34) and subsequent use of this term throughout the proposed rule.

2. **Key Product Prioritization Factors Should Meaningfully Assess Exposure**

AB1879 requires the establishment of an identification and prioritization process that includes "the potential for exposure to the chemical in the consumer product". The proposed regulations do not effectively take into account the potential for exposure in the key prioritization factors. Further, a clear step-by-step process for how the Department will use these criteria to prioritize products is not included. We recommend that DTSC improve the key product prioritization criteria in § 69503.2(b) to ensure that this legislative mandate is achieved.

The product prioritization factors in § 69503.2(b) are overly reliant on market presence information for the product and use of the product as surrogates to assess exposure. For complex articles, like electronic products, exposure to, or use of, the *product* itself often does not equate to exposure to the *chemical*. For example, the chemical of concern may be used in an inaccessible component part.

In order to effectively meet the mandate of AB1789, we urge DTSC to include an effective way to assess exposure *to the chemical* in the product in the **key prioritization factors**. We provide a recommendation below that we believe would accomplish this.

We would also recommend that DTSC provide additional clarification to one of the criterion in § 69503.2(a). "Containment of the Chemical(s) of Concern within the product" is a factor listed for DTSC to consider in product prioritization. Helpful clarifying language is included in the initial statement of reasons (ISOR) that describes that "how the Chemical of Concern is contained or bound during the use of the product determines, in part, the amount of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user, in which case, there is little to no exposure as a result of use of the product." This approach is consistent with that taken in similar regulations that regulate chemicals in children's product, such as US CPSIA. This statement should be retained in the final statement of reasons. We recommend that language consistent with that in the ISOR be included in §69503.2(a)(1)(B)4 of the rule itself to clarify that the concept of accessibility would be included in considering "containment of the chemical".

We believe that the recommendations below will help to not only meet the mandate of AB1879 but also to focus Department and industry resources on those uses of chemicals in consumer products that are of most concern to the citizens and environment of California.

RECOMMENDATION:

§ 69503.2.(b) Key Prioritization Factors. The Department shall, based on available information, give priority to products meeting both of the following criteria:

(1) The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts; and

(2) There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce, and how widely the product is used by consumers, **and whether consumers may have potential inhalation or dermal contact with the chemical of concern in the product or component during normal and reasonably foreseeable use of the product.**

§ 69503.2(a). Containment of the Chemical(s) of Concern within the product, **which includes whether the Chemical(s) of Concern is in an inaccessible component within a product;**

3. **Alternative Assessment (AA) Cumulative Threshold Concerns**

We support the modification in the July 2012 proposed rule, which clarifies that DTSC will specify a single AA threshold which may refer to a group of substances with the same hazard trait during the Priority Product listing process vs. leaving it up to industry to decide which chemicals should be summed together to determine whether or not the AA threshold is triggered. However, we share the concerns identified in the ITI, TechAmerica, CEA, and SIA comments about the complexity of including the cumulative chemical effect concept within the Alternatives Analysis Threshold determination phase. This concept would be more appropriately handled in the product prioritization phase or regulatory response phase of the regulation. In addition, it is not clear if DTSC's intent is to regulate within a single chemical family (e.g. phthalates) or across multiple chemical families (e.g. inorganic and organic chemicals). The cumulative threshold concept is only practical if it is focused on a single chemical family where it is difficult to differentiate between substances using known analytical methods.

RECOMMENDATION:

We recommend that the cumulative chemical concept be removed from the Alternative Analysis Threshold determination and § 69503.5 (d) Alternatives Analysis Threshold Exemption and addressed at a more appropriate phase in the regulation.

If the cumulative chemical concept is kept in the regulation, it should be clarified that the cumulative threshold will only apply to chemicals within the same chemical family (e.g. phthalates) that exhibit the same hazard trait.

4. **Remove the Alternative Assessment (AA) Threshold Exemption Notification**

Intel supports ITI, TechAmerica, CEA and SIA comments recommending that the threshold exemption notification process should, at a minimum, be self-implementing. As proposed, this provision will require significant DTSC and industry resources to demonstrate that chemicals are not present in significant quantities. It will divert attention away from the true intent of the program, which is the alternative assessment process and ultimately safer consumer product designs. Because the proposed rule would require DTSC to establish an appropriate alternative assessment threshold for each Chemical of Concern-Priority Product pairing, it is not necessary for DTSC to have to further administer an AA threshold exemption notification process. Presumably DTSC would have collected reliable information

on levels of the chemical in the product in order to determine the appropriate threshold level, making the additional exemption notification process redundant.

RECOMMENDATION:

Remove § 69503.6. Alternatives Analysis Threshold Exemption.

5. Chemical of Concern Removal Notification Concerns

As proposed, the Chemical of Concern Removal Notification may not meet the intent of the rule to encourage innovations and safer consumer products. A chemical of concern removal notification may only be submitted if a responsible entity "reformulates the Priority Product to remove a Chemical(s) of Concern, that is/are the basis of the Priority Product listing, **without adding a substitute chemical...**". The prohibition of all chemical substitutions may be too restrictive. If a product is reformulated to remove a chemical, it is unclear how a manufacturer would not have a substitute chemical to replace the function of the original chemical of concern, so this provision would never be met in practice. For example, our experience with EU RoHS showed that removing lead solder from a product required the replacement a different solder chemical to fulfill the same function as the original lead solder.

Therefore, this provision, as currently drafted, would not meet the intent of encouraging companies to reformulate products without using a chemical of concern as such a reformulation would almost always require a substitute chemical to replace the same function as the original chemical of concern. We believe that DTSC's intent with this provision is to encourage replacement of chemicals of concern and the development of safer consumer products and to allow for this provision to be used in practice by industry leaders.

RECOMMENDATION:

Modify the Chemical of Concern Removal Notification to allow for the intent of the provision:

§ 69505.1.(g) Chemical of Concern Removal Notification. If a responsible entity reformulates the Priority Product to remove Chemical(s) of Concern, that is/are the basis for the Priority Product listing, without adding a substitute Chemical **of Concern previously listed for that consumer product**, the responsible entity may submit a Chemical of Concern Removal Notification to the Department in lieu of conducting an AA and submitting an AA report.

6. Clarify that a Priority Product Must Contain a Chemical of Concern

The Initial Statement of Reasons (ISOR) is clear that products that do not contain a chemical of concern are not subject to the requirements of this chapter. However, the regulations are not clear on this key point.

RECOMMENDATION:

Modify § 69501.1.(48) "Priority Product" means a product **containing one or more Chemical(s) of Concern** as identified and listed as a Priority Product by Department under section 69503.4

7. **A De Minimis Threshold Should Be Included**

Based on Intel's 10-yr experience with the Joint Industry Guide (JIG) 101 electronic industry material declaration standard, we have learned that having a consistent list of declarable substances and consistent de minimis reporting thresholds is critical for ensuring timely and accurate part level chemical content data transfer throughout the supply chain. The information developed through these systems forms an important basis for environmentally conscious product design in the industry.

Allowing the threshold for each Chemical of Concern/Priority Product to be set on a case-by-case basis does not provide industry with sufficient predictability to establish effective supply chain chemical information exchange systems. Lack of true de minimis threshold in CA Safer Consumer Products regulations will add unnecessary complexity which in turn will make the regulation more difficult to implement, but will not necessarily result in any increased environmental or human health benefit.

Consequently, Intel supports previous comments submitted by ITI and TechAmerica supporting the inclusion of a de minimis threshold aligned with existing chemical regulations, such as the EU REACH Regulation and the Globally Harmonized System (GHS) for chemical reporting. This will allow the agency to focus its limited resources on the most significant uses of Chemicals of Concern (COC) and allow for faster implementation as responsible entities will be able to utilize reporting systems already in place. The de minimis threshold is an effective mechanism that is used across many existing rules regulating chemicals to ensure that valuable resources are not focused on proving negatives and are, instead, focused on achieving shared environmental goals.

Intel appreciates the opportunity to comment on the draft regulations. If you have any additional questions, please do not hesitate to contact me at linda.young@intel.com or 480-552-9280.

Sincerely,



Linda S. Young
Corporate Product Regulations & Standards (CPRS)
Manager, Product Ecology

October 11, 2012

VIA E-MAIL (GCREGS@DTSC.CA.GOV)

Krysia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: iGPS Comments on Proposed California Safer Consumer Products Regulations (R-2011-02)

Dear Ms. Von Burg:

On behalf of our client, Intelligent Global Pooling Systems Company, LLC (“iGPS” or the “Company”), we appreciate the opportunity to submit comments regarding the Safer Consumer Products regulations being proposed by the California Department of Toxic Substances Control (“DTSC”) (Department Reference Number R-2011-02). Sustainability is a core value of iGPS, and we share in DTSC’s goal to promote a sustainable future. These comments contain suggestions to improve the proposed regulatory scheme through the further promotion of recycling and the focusing of agency and private resources where they are most needed in the product prioritization process.

I. Background on iGPS

iGPS is the operator of the world’s first pallet rental service providing lightweight, sustainable plastic shipping pallets. The Company is not itself a chemical manufacturer or processor. iGPS does, however, purchase (and lease to its customers) plastic shipping pallets that are produced using a highly specialized fire-resistant polymeric matrix that includes a specialized flame retardant compound which is embedded as a minor component in the polymer matrix to ensure compliance with strict fire safety standards. In addition to meeting these standards, iGPS’s pallets are lighter, stronger, and safer than the traditional heavy wood shipping pallets that remain the predominant type of pallet in commerce to this day. iGPS’s pallets also have an environmental profile which an independent life cycle analysis has determined to be far

Kryisia Von Burg
October 11, 2012
Page 2

superior to wood pallets.¹ Embedded radio frequency identification devices (RFID technology) enable the iGPS pallets to be traced and tracked throughout the supply chain.

Sustainability is a defining feature of iGPS's pallets and of iGPS's business model. iGPS's pallets remain reusable for a period of time well beyond that of traditional wood shipping pallets. Indeed, iGPS's pallets are never disposed because at end of life they are recycled into new pallets. When damaged beyond repair, iGPS pallets are taken out of service and ground or shredded, and then re-molded into new plastic pallets. In this way, iGPS follows the environmentally sound and socially responsible practice of "cradle to cradle" sustainability. This recycling practice drives iGPS's business model and its customers' preference for iGPS pallets over alternatives.

II. Comments on Proposed Regulations

A. The proposed regulations should be modified to further encourage the environmentally beneficial practice of recycling.

In several places in the proposed regulations, DTSC wisely recognizes the importance of recycling and incorporates measures to promote it. For example, when setting a threshold for a chemical of concern ("COC") in a potential Priority Product for which an alternatives analysis ("AA") could be required,² DTSC must consider how difficult it is to remove the COC from the potential Priority Product when that COC is commonly present in the product as a "contaminant" in recycled materials used to manufacture the product. Proposed Regulations ("PR") § 69503.5(c)(1)(C). In addition, DTSC requires that a second stage AA³ must compare the life cycle costs associated with the Priority Product and alternatives, including end of life costs, where "life cycle" is defined to include product recycling. PR §§ 69505.4(a)(2)(C), 69501.1(a)(39). The proposed regulations also require that increased recyclability be a goal for product stewardship plans for selected alternatives. PR § 69506.8(a)(2)(A)(8)(b).

iGPS supports the incorporation of recycling principles into the proposed regulatory scheme. As DTSC recognizes in the Initial Statement of Reasons associated with the proposed regulations, "[r]ecycling materials conserves natural resources and

¹ See <http://www.igps.net/advantage/lca.php>.

² In the proposed regulatory scheme, AAs need not be conducted if the concentration of a COC in a product is below a DTSC-determined alternatives analysis threshold.

³ The proposed regulatory scheme requires AAs to be performed in two stages, with DTSC approval required after the first stage. See PR § 69505.1.

ARNOLD & PORTER LLP

Krysia Von Burg
October 11, 2012
Page 3

energy, promotes sustainability, reduces disposal to landfills, and reduces the use of virgin material.” Initial Statement of Reasons (“ISOR”) at 107. Given the environmental significance of recycling practices, DTSC must carefully consider any program element that would discourage recycling and as a result potentially increase wasteful practices.

In that vein, iGPS believes that DTSC has not fully considered how the proposed regulatory scheme may inadvertently discourage recycling. The current proposed regulations provide very limited relief for companies utilizing recycled materials that would allow them to avoid being swept into the alternatives analysis and product replacement process. The only potential relief provided in the proposed regulations is that DTSC must consider the difficulty of removing COCs from recycled materials when setting alternatives analysis thresholds. Despite this consideration, the fact that the presence of COCs in recycled materials could trigger an obligation to perform an alternatives analysis may discourage use of many classes of recycled raw materials altogether. Entities who rely on recycled materials may abandon their use rather than risk being caught up in the regulatory process. These materials might then be simply disposed in landfills or through other waste management methods such as incineration. Reverting to use of newly-manufactured materials would result in increased natural resource and energy use from the production of virgin materials as well as increased costs.

To balance the important objectives of recycling with those of the Safer Consumer Products regulations, iGPS asks that DTSC entirely exclude COCs present in recycled materials from the scope of the proposed regulatory scheme. A recycled materials exemption would simplify the regulatory processes and provide security to the users of recycled materials that they would not be swept into the new regulatory scheme as a result of the environmentally beneficial practice of recycling. This approach also is consistent with the otherwise forward-looking orientation of the proposed regulations. Just as the regulations do not cover “historic products,” the program need not seek to regulate COCs historically added to recycled materials. The program can effectively achieve its goal of COC exposure reduction while also exempting from consideration COCs that are present in recycled materials and products.

If DTSC chooses not to exempt COCs present in recycled materials, DTSC should at least explicitly require that AAs consider the effects of switching to an alternative on the opportunities to make beneficial use of recycled materials. While the current proposed regulations do require the examination of materials and resource consumption impacts, PR § 69505.4(a)(2)(A), they do not specifically require that an analysis consider whether switching to an alternative might eliminate the use of a recycled raw material stream, and the attendant loss of environmental benefits. This

Krycia Von Burg
October 11, 2012
Page 4

environmental factor must be weighed against any potential decreases in exposure to a COC obtained by eliminating uses of recycled materials containing a COC.

In addition, if DTSC does not provide a recycled materials exemption, it should eliminate the use of the term “contaminant” in § 69503.5(c)(1)(C) of the proposed regulation. As drafted, the proposal only requires DTSC to consider the existence of COCs present as “contaminants” in recycled materials when setting alternatives analysis thresholds. This appears inconsistent with DTSC’s position in the Initial Statement of Reasons that the threshold will apply to both intentionally and unintentionally added chemicals. ISOR at 105. Further, DTSC does not define “contaminant.” To avoid confusion, if consideration of COCs present in recycled materials is not completely exempted from the regulation, then iGPS asks that DTSC modify the proposed regulation to require consideration of all COCs present in recycled materials when setting alternatives analysis thresholds, not just those present as “contaminants.”

B. DTSC should amend the Priority Product list regulations to ensure that resources are better allocated to where they are most needed.

DTSC’s proposed regulations seek to identify Priority Products for which regulation is most appropriate. iGPS believes, however, that there are at least two ways in which the proposed listing process could be modified to better achieve DTSC’s goals.

First, DTSC has rightly chosen to focus its regulatory efforts on consumer products, as this class of products is most likely to come into direct contact with the vast majority of the population. Despite the broad definition of “consumer product” incorporated into the proposed regulations,⁴ DTSC has wisely included elements in the prioritization process that focus on how real consumers are affected by COCs, such as examination of the degree of household presence of a COC in a particular product and how widely a product is used by consumers. PR §§ 69503.2(a)(1)(B)(3), 69503.2(b)(2). To further ensure that the regulatory scheme truly prioritizes products that most directly affect consumers, iGPS believes that DTSC should only evaluate products that are sold or distributed to consumers. Such an exemption would maximize efficient resource allocation by focusing on the most significant subset of products from an exposure and

⁴ The statutory definition of “consumer product” relied on by DTSC is “a product ... used, brought [sic.], or leased for use by a person for any purpose.” Cal. Health & Safety Code § 25251(e). “Person” is further defined to include corporations and other business organizations. Cal. Health & Safety Code § 25118. Thus, the definition of consumer product by itself is divorced from the concept of a consumer, and thus appears internally inconsistent.

Kryisia Von Burg
October 11, 2012
Page 5

risk perspective. Doing so would be consistent with the underlying purpose of the regulations (the Safer Consumer Products regulations) and with other portions of the proposed regulations that emphasize consumer exposure. See, e.g., PR § 69501.1(a)(55) (definition of retailer limited to entities dealing with consumers). Extending the scope of the regulations beyond products that are sold or distributed directly to consumers also wastes resources because other categories of exposures, such as workplace exposures, are governed by separate legal and regulatory schemes. Though the prioritization process takes these other legal requirements into account, it would be more efficient for DTSC to specifically exclude from the prioritization process any consideration of products that have only commercial and industrial uses in order to focus only on those products that directly come into contact with consumers.

Second, DTSC correctly includes consideration of the degree to which other California, federal, or applicable international law may already provide adequate protection with respect to certain COCs. As part of this review, DTSC should be sure to consider the existence of voluntary agreements by which entities that produce a COC have established a commitment with regulators to phase out the manufacture or importation of a particular COC.⁵ Recently, the United States Environmental Protection Agency in particular has effectively established a number of voluntary agreements by which manufacturers and importers have committed to terminate production of certain substances that might be considered by DTSC for listing as potential COCs. Failure to consider the existence of these agreements could again result in the waste of limited state and private resources on evaluating products that already are in the process of being phased out of use in the U.S..

* * *

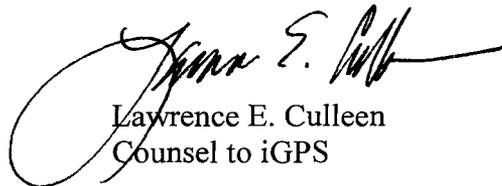
⁵ See, e.g., <http://www.epa.gov/opptintr/pfoa/pubs/stewardship/index.html> (describing producers' commitment to achieve a 95% reduction by 2010, and to work toward the elimination of PFOA, PFOA precursors, and related higher homologue chemicals from emissions and products no later than 2015).

ARNOLD & PORTER LLP

Krycia Von Burg
October 11, 2012
Page 6

iGPS appreciates the opportunity to comment on the proposed Consumer Products Safety regulations. We hope that DTSC will take our comments into consideration to ensure the final requirements effectively promote recycling and focus on the products most likely to affect consumers.

Sincerely,



Lawrence E. Cullen
Counsel to iGPS

cc: Bruce Torrey, iGPS



October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives
Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulations

Dear Ms. Von Burg:

The International Fragrance Association, North America (IFRA North America) would like to express its appreciation to the California Department of Toxic Substances Control (DTSC) for the opportunity to comment on its draft Safer Consumer Product Regulations (Regulations). IFRA North America represents the fragrance industry in the United States. Our companies create and manufacture fragrances for personal care, home care, industrial and institutional use as well as home design products, all of which are manufactured by consumer goods companies. Our association also represents companies that supply individual fragrance ingredients, such as essential oils and other raw materials, which are used in perfumes and fragrance mixtures.

IFRA North America remains fully supportive of the principles behind the Regulations. As you know, our industry is committed to the protection of public health and the environment worldwide. While we believe DTSC has achieved critical improvements in the latest version of the Regulations, we appreciate the opportunity to provide comments on areas we believe could be further improved. In addition to the comments outlined below, we echo and support the industry coalition document submitted to DTSC, 'Principles of Alternatives Assessment', to which IFRA North America is a signatory.

INTERNATIONAL FRAGRANCE ASSOCIATION
NORTH AMERICA
1001 19th Street North, Suite 1200
Arlington, VA 22209
Tel: 571.346.7580
Fax: 571.384.7959
www.ifrana.org

A series of thin, overlapping wavy lines in various colors (blue, green, purple, red) that flow across the bottom of the page from left to right.

IFRA North America has designed its comments to focus on three areas of the regulations that are the most fundamental to our industry. These include: the Chemicals of Concern (CoC) List, the Alternatives Analysis Threshold (AA Threshold), and the protection of confidential business information (CBI). Each of these aspects is discussed in more detail below. We remain hopeful that the inclusion of our comments in the final regulations will result in an intersection agreeable to businesses, government entities, public interest groups, and most importantly, consumers.

Chemicals of Concern Identification Process

IFRA North America was pleased to learn of DTSC's intent to generate a more focused list of CoCs in the latest version of the Regulations. However, we believe there still remains a need for transparency in the explanation of why certain substances will be chosen using the "list of lists" approach. We urge DTSC to publish a set of conceptual criteria of how the larger CoC list will be selected, as well as how the narrowed chemicals of "higher" concern will be selected. This will assist industry in understanding why certain chemicals will be selected over others, likely resulting in more conscience choices moving forward.

As it relates to the selection of chemicals on the CoC list, IFRA North America respectfully requests DTSC to define the term 'authoritative bodies.' It is extremely important that there be a clear definition of what constitutes an authoritative body.

Furthermore, IFRA North America has concerns that some of the sources relied upon to compile the CoC list have not yet made final determinations in identifying the known or likely hazards of a number of substances. For example, a European Commission Directorate-General for the Environment (DG Environment) report simply identifies chemicals that DG Environment believes should be given priority *for further investigation regarding their potential* to be endocrine disruptors. In collecting data from sources to assemble the CoC list, IFRA North America suggests DTSC ensure that information that it references, and on which it relies for regulatory action is conclusive and irrefutable, and not in a state of flux.

Finally, IFRA North America is compelled to insist on a different terminology when referring to the CoC List. "Chemicals of Concern" inherently carries a negative connotation when it has not yet been determined for all 1200 chemicals if there is, in fact, a concern regarding potential risk. Instead, we recommend calling the list "Chemicals under Consideration." This would alleviate the worry of the "black list effect" which could cause our industry significant harm, especially if DTSC determines that no regulatory action is necessary for the chemical.



Alternatives Analysis Threshold

IFRA North America is concerned that the Regulations do not include a fixed 'de minimis' level for an AA threshold and instead would require DTSC to determine the threshold on a case by case basis. We have serious reservations with this change as DTSC would now have wide latitude in setting such levels thus resulting in further uncertainties for both large and small businesses alike. Further, the process by which this is determined will be not only incredibly time consuming, but could also be highly politicized. Instead, we urge DTSC to establish a default level consistent with numerous State, Federal and global regulations, including the Globally Harmonized System for product classification which sets a threshold of 0.1% concentration of an intentionally-added chemical in a finished product. To default to any detectable concentration of a potential CoC is unreasonable and not even necessarily quantifiable.

IFRA North America supports the inclusion of a 'de minimis' concentration of 1000 parts per million of an intentionally-added chemical in a finished product, which is consistent with other international regulatory requirements. In the event that an entity believes the threshold should be changed for a particular chemical in a particular product, IFRA North America would be supportive of a stakeholder process which allows for this request to be made.

Another major concern we have with the proposed Regulations is the absence of a clear and articulated exit process for chemicals that fall under the AA threshold. As you know, fragrance formulations typically account for a diminutive minority of the total composition of a consumer product. As such, it is reasonable to expect that, in many cases, an alleged chemical of concern contained in a fragrance in a consumer product would not meet the AA Threshold. We respectfully request that DTSC acknowledge and establish a defined process applicable to cases where the concentration of a CoC falls outside of the minimum threshold set for a product, and in doing so, is mindful of the administrative burden that would fall on industry.

INTERNATIONAL FRAGRANCE ASSOCIATION
NORTH AMERICA

1001 19th Street North, Suite 1200
Arlington, VA 22209
Tel: 571.346.7580
Fax: 571.384.7959
www.ifrana.org

A decorative graphic at the bottom of the page consists of several overlapping, wavy lines in various colors (blue, green, purple, red) that flow from the left side towards the right, ending in a slight upward curve.

Protection of Confidential Business Information

IFRA North America applauds the efforts made by DTSC concerning the protection of CBI. We are appreciative that DTSC understands the fundamental importance that trade secrets hold for our unique industry. Yet, in some cases, we believe this CBI will not be adequately protected, specifically as it relates to the AA development. Our members have raised concerns that a chemical's identity could be disclosed during this process. While we commend DTSC on including provisions that permit companies to claim information as CBI, those same provisions also require the public filing of redacted information which could result in divulging valuable proprietary information. We believe unique provisions to protect CBI are warranted; therefore we encourage DTSC to allow manufactures of the chemical in question to use generic names throughout the AA process. This would still allow the public to review the properties and characteristics of the material while not compromising the intellectual property that is so crucial to our industry.

Additionally, IFRA North America requests that DTSC remove the provision in the section related to the assertion of a trade secret as it relates to reverse engineering. We do not believe that the ease or difficulty of discerning a chemical through reverse engineering should have any bearing on the legitimate legal protections provided by trade secret provisions. This is not relevant and therefore should be eliminated in the final regulations.

Conclusion

IFRA North America supports the aim of DTSC to institute safeguards for both consumers as well as the environment. Nonetheless, we would be remiss if we did not make DTSC aware of the difficult challenges that will face our industry as the regulations are currently written. We remain optimistic that a balance will be achieved in the final regulations and that the above comments are helpful to DTSC as the draft regulations continue to be revised.

Sincerely,

A handwritten signature in black ink, appearing to read "Jennifer Abril". The signature is fluid and cursive, with the first name being more prominent.

Jennifer Abril
President



Government Relations
1901 N. Moore Street, Suite 600
Arlington, VA 22209

703-522-0225 tel
703-522-0543 fax
www.ipc.org

October 11, 2012

Ms. Krysia Von Burg
Safer Consumer Product Alternatives Regulation Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)

Dear Ms. Von Burg:

IPC – Association Connecting Electronics Industries appreciates the effort DTSC has invested in developing the above referenced Safer Consumer Product Alternatives Regulation. IPC is, however, seriously concerned that the proposed regulation, due to its unwieldy and unimplementable scope, will fail to improve the health and safety of California's citizens. IPC, in concurrence with the Green Chemistry Alliance (GCA), of which we are a member, strongly recommends that DTSC consider a more focused program that concentrates on the substances in consumer products most likely to pose significant risks to human health and the environment. We appreciate the opportunity to provide the following comments which detail our concerns.

IPC, a U.S. headquartered global trade association, represents all facets of the electronic interconnection industry, including design, printed board manufacturing and electronics assembly. Printed boards and electronic assemblies are used in a variety of electronic devices that include computers, cell phones, pacemakers, and sophisticated missile defense systems. IPC has over 3,200 member companies, including over 370 member companies located in California.

IPC strongly supports cost effective, science-based environmental initiatives and has been active in a number of voluntary environmental programs including several of EPA's Design for the Environment partnership projects, the development of the Electronic Product Environmental Assessment Tool (EPEAT) standard¹, and the development of the Greener Chemicals and Process Information Standard², developed through the American Chemical Society and National Standards Foundation.

IPC believes that the proposed regulation will fail to improve the health and safety of California's citizens because the proposed scope is unmanageable. We believe that a more focused regulatory approach would better achieve the goals of the legislation and allow DTSC to

¹ <http://www.epeat.net/>

² NSF/GCI/ANSI 355

http://www.nsf.org/business/sustainability/product_greener_chemicals.asp?program=Sustainability

effectively use available resources to focus on those chemicals most likely to cause adverse impacts to the public. Should DTSC wish to expand the scope of chemicals of concern in the future, a phased-in approach would ensure that all chemicals of concern are eventually covered in the regulation. Implementation of a more manageable approach to a green chemistry regulation will help to improve the health and safety of the citizens of California.

In order for DTSC to develop an effective regulation, the agency should identify and prioritize chemicals of concern in consumer products based on **exposure and hazard**. The proposed regulation proposes to use a list-of-lists approach to selecting chemicals of concern. DTSC predicts the list to be over 1200 chemicals. *This approach is seriously flawed and unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemicals.* Substances that exhibit the greatest hazards, such as those known to cause cancer, developmental or reproductive harm, be persistent, bioaccumulative and toxic (PBT) in the environment, and pose the greatest exposure to consumers, should be given priority. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on exposure and hazard.

IPC supports DTSC's decision to initially focus the regulation on no more than five Priority Products. This is a practical approach that will enable DTSC to implement this unique program and to learn what works and does not work and make adjustments accordingly. A regulation that is focused on a small number of specific product categories will allow DTSC to use available resources more efficiently and implement a manageable regulation.

Despite DTSC's efforts to focus on a small number of product categories, the agency has proposed a regulatory scheme that exceeds what its own resources can effectively support. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement. IPC is concerned that complete, appropriate enforcement and implementation of this proposed regulation may be beyond the current capacities of the state. DTSC must ensure that they have the appropriate programs in place to ensure the regulation is effectively implemented in order to ensure the least amount of burden is put on industry.

In conclusion, it is essential for DTSC to scale down the scope of the proposed regulation in order to implement a feasible regulation. If DTSC attempts to take on too much at one time, the entire program may fail. DTSC, industry and citizens of California would be better served by a program that implements a phased-in approach to chemicals regulations.

We appreciate your consideration of our concerns. For further information or questions, please contact me at scastorina@ipc.org or (703) 522-0225.

Sincerely,



Stephanie Castorina

Manager, Environmental Programs

CC: The Honorable Matt Rodriguez, Secretary, CalEPA
Miriam Ingenito, Deputy Secretary, CalEPA

Kristin Stauffacher, Assistant Secretary, CalEPA
Nancy McFadden, Cabinet Secretary, Office of the Governor
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor
Cliff Rechtschaffen, Senior Advisor, Office of the Governor
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



Japan Chemical Industry Association
Sumitomo Rokko Bldg. 1-4-1 Shinkawa, Chuo-ku, Tokyo 104-0033, Japan
Telephone: +81-3-3297-2567, Fax: +81-3-3297-2612
URL: <http://www.nikkakyo.org/>

October 11, 2012

Ms. Krysia Von Burg
Regulations Coordinator, Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Re: Safer Consumer Products Draft Regulation (July 27, 2012)

Dear Ms. Von Burg:

On behalf of the Japan Chemical Industry Association (JCIA), we respectfully submit the following comments relative to the Department of Toxic Substances Control's (DTSC) draft Safer Consumer Products Regulation of July 27, 2012.

JCIA, which has about 170 member companies and about 80 organizations engaged in the manufacturing and handling of chemical products, promotes the stable development of the chemical industry in Japan and beyond. As a member of the International Council of Chemical Associations (ICCA), consisting of the world's chemical associations, JCIA has engaged in voluntary global initiatives to resolve issues faced by chemical companies and associations throughout the world, including matters related to the environment, the safety of chemicals, and measures to prevent global warming.

JCIA is grateful for the opportunity to comment on the proposed regulations described in the above title. These regulations are aimed to promote the replacement of consumer products containing chemicals of concern (COC) with alternative products, in the efforts towards green chemistry initiatives, which search for safer chemicals. However, the proposed regulations have some problems, as summarized below, causing serious concern for us. We hope that appropriate measures are taken to address these concerns.

1. Chemical of Concern List (COC List)

According to the "Safer Consumer Products, Summary of Proposed





October 11, 2012

Page 2

Regulations,” a document released at the same time as the proposed regulations, approximately 1,200 substances are expected to be included in the initial COC list. Priority consumer products containing COCs would be required to be replaced with alternative products, which raises a concern that the COC list will become a black list, and that manufactures, importers, and retailers handling COCs and COC-containing products, especially small and medium-sized enterprises, will be significantly affected.

JCIA understands that DTSC intends to issue a shorter list of COCs, which will be the focus of DTSC efforts until 2016. While a shorter list of COCs is preferable to the initial 1,200 substance list, it is still unusually large in comparison with the number of substances listed as COC in different countries. There are 83 substances listed as TSCA Work Plan Chemicals by the U.S. Environmental Protection Agency (EPA) in the U.S. (as of March 2012), 84 are listed as substances of very high concern (SVHC) in the European Union’s (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations (as of June 2012), and 95 are listed as Priority Assessment Chemical Substances in the Japanese Chemical Substances Control Law (as of March 2012). The estimated number of substances to be listed in the initial focus list of COCs for the case in question is much larger than these other lists, causing great concern over the impact on business activities and society in general.

Therefore, in regards to the selection of substances to be included in the COC list, we request that a strengthened and more rigorous selection system be put in place, including prioritization in a stepwise fashion, so that the number of substances subjected to the regulations can be minimized.

At a minimum, JCIA urges DTSC to provide a clear disclaimer that inclusion on the COC list is NOT a determination by DTSC that the chemical in question is a concern in any particular product.

2. Alternatives Analysis (AA)

To accommodate the proposed regulations, many complicated steps must be followed, from the release of the initial COC list to the final stage of complying with regulatory responses. In particular, with regard to preliminary analysis and final analysis of the alternatives



October 11, 2012
Page 3

in the priority products (PP), the following difficulties are anticipated. First, it is expected that a long period of time will be required for businesses to confirm the functions, quality, safety, and so on, of products to which alternatives have been introduced. Therefore, the submission deadline for the preliminary analysis report (180 days after the release of the PP list) is too short. The deadline should be extended to several years.

The training and securing of assessors in accordance with the required certification criteria would be difficult, and the practicability of this requirement is uncertain, especially for small and medium-sized enterprises. The entire assessor system should be eliminated from the regulations. If that is not possible, the certification criteria must be revised. DTSC should recognize that there are many people familiar with AA assessments that would not qualify as an assessor because the proposed regulations require “a Bachelor’s degree with a major in a scientific or engineering field from an accredited college or university.”

3. Responsibility for compliance with the regulations

Section 69501.2 of the proposed regulations states that the regulatory requirements may be fulfilled by a consortium, trade association, or other entity acting on behalf of the manufacturer, importer, or retailer, except for certain requirements such as the Priority Product Notification. JCIA fully supports this option as it will provide the most effective manner for its members to engage in the regulatory process. We further urge DTSC expressly to encourage consortia formation in response to the regulation. This would reduce costs and resources to industry, as well as to DTSC which would only have to review one consortium-generated assessment, versus multiple assessments from individual companies. We note, however, that DTSC needs to provide more information on conditions and operation procedures for consortia formation, as they are not described in the proposed regulations.

We request therefore that provisions pertinent to entities that may fulfill the requirements in lieu of the responsible entities be established.



Japan Chemical Industry Association
Sumitomo Rokko Bldg. 1-4-1 Shinkawa, Chuo-ku, Tokyo 104-0033, Japan
Telephone: +81-3-3297-2567, Fax: +81-3-3297-2612
URL: <http://www.nikkakyo.org/>

October 11, 2012

Page 4

For further information regarding the Japan Chemical Industry Association, please visit the JCIA website at <http://www.nikkakyo.org/>

Sincerely Yours,

A handwritten signature in black ink, appearing to read 'Fumiaki Shono', with a large, sweeping flourish extending to the left.

Fumiaki Shono, Ph.D.

Executive Director

Chemicals Management Department

Japan Chemical Industry Association



GCREgs@DTSC

From: TAKIMI KAZUYUKI <kazuyuki.takimi@mofa.go.jp>
Sent: Wednesday, October 10, 2012 8:25 AM
To: GCREgs@DTSC
Subject: Comment by Japan on Safer Consumer Product Alternatives of the California State Government
Attachments: Comment by Japan.DOCX

Dear Ms. Krysia Von Burg,

Good morning.

Please find attached file regarding Japan's comment on Safer Consumer Product Alternatives of the California State Government.

It would be much appreciated if you would let me know that you have received it.

Best,
Takimi

Kazuyuki TAKIMI (Mr.)
Economic Section, First Secretary
Embassy of Japan
2520 Massachusetts Ave., N.W. Washington DC 20008
Phone: 202-238-6729(direct)
Fax: 202-265-9473
Mobile: 202-215-3019

Comment on Safer Consumer Product Alternatives of the California State Government in the United States of America

9 October, 2012

The Government of Japan would like to express its sincere appreciation to the California State Government and the Government of the United States of America for the extension of the deadline for submission of Japan's comments on the TBT notification (G/TBT/N/USA/727) regarding Safer Consumer Product Alternatives to October 11, 2012. Japan would like to strongly request that the Department of Toxic Substances Control (DTSC), California and the United States thoroughly examine following concerns expressed by Japan and take them into account for further considering the new legislation.

1. Technical regulation on unspecified subjects

The proposed regulation is intended to require analysing the hazardous properties of chemicals of concern used in consumer products and to consider replacement of them with alternatives when they may be hazardous based on the analysis in order to control consumer products. However, the proposed regulation describes neither subject consumer products nor chemicals of concern clearly. The Article 2.9.2 of the TBT Agreement provides that "Members shall notify other Members through the Secretariat of the products to be covered by the proposed technical regulation." For all with this provision, it appears that the covered products are not specified enough in the TBT notification (G/TBT/N/USA/727). In addition, due to the unspecified description of consumer products and chemicals of concern, it would be impossible to sufficiently assess whether the proposed regulation would have the effect of creating unnecessary obstacles to international trade and whether it would be more trade-restrictive than necessary to fulfill a legitimate objective.

Therefore, Japan would like to request that California and the United States should submit TBT notification once again after specifying consumer products and chemicals of concern. Japan will assess the effect of this regulation again based on the follow-up TBT notification.

2. Concerns and comments of industries in Japan

Japan is aware that several industries in Japan are also concerned that the proposed regulation, which covers the wide range of substances, could have a negative impact on the global economy and international community when considered current global distribution system. Japan is also aware that the following Japanese industrial associations have submitted some comments on the public comment of California. Therefore, Japan hopes that the DTSC seriously consider the comments by Japan and Japanese industries.

<The list of industrial associations that has submitted comments>

JEITA (Japan Electronics & Information Technology Industries Association)

CIAJ (Communications and Information Network Association of Japan)

JBMIA (Japan Business Machine and Information System Industries Association)

JEMA (Japan Electrical Manufacturers' Association)

JCIA (Japan Chemical Industry Association)

Japan greatly appreciates cooperation of the California and the United States in responding to the comments and concerns raised by Japan and Japanese industries. Japan looks forward to reply of the California and the United States.

GCREgs@DTSC

From: m-sato@jeita.or.jp
Sent: Friday, September 28, 2012 1:55 AM
To: GCREgs@DTSC
Subject: Comments on Safer Consumer Product Regulations
Attachments: Comments on Safer Consumer Product Regulations_JP_20120928.doc

Categories: Comment

Dear Ms. Krysia Von Burg,

We send you our comments on Safer Consumer Product Regulations.

Please find the attachment.

Best Regards,

Minoru Sato
Secretariat of the Chemical Regulations Committee of 4 Japanese industry associations.

4 Japanese industry associations are as follows.

JEITA (Japan Electronics & Information Technology Industries Association)
CIAJ (Communications and Information Network Association of Japan)
JBMIA (Japan Business Machine and Information System Industries Association) JEMA (Japan Electrical Manufacturers' Association)

Minoru Sato
Japan Electronics & Information Technology Industries Association
(JEITA)
Ote Center Bldg.
1-1-3,Otemachi,Chiyoda-ku,Tokyo 100-0004,Japan URL <http://www.jeita.or.jp> <mailto:m-sato@jeita.or.jp>

4 Japanese industry associations Comments on Safer Consumer Product Regulations

28 September 2012

"Comment on whole legislation"

page	Clause/ Subclause	Comments	Proposed change
		<p>The draft regulation is supposed to be unreasonable trade barrier, as regulatory impact is unable to assess: draft regulation should clearly state subject product(s) and chemical(s), assess regulatory impact with socio-economical consideration, and to be placed on public comment.</p> <p>Draft Safer Consumer Products regulation is nominally intended to regulate all consumer products, requires Alternate Analysis(AA)/ replacement of certain chemical with alternative based on hazard property of the chemical, and there are no similar regulation around the world. Essentially, AA with consideration of risk tradeoff described in the draft regulation have difficulty with verification of scientific evidence, and there are great technical uncertainty on the implementation of the substitution of the chemical. Furthermore, AA will be time consuming and requires unaffordable burden, however benefit to be earned will have great uncertainty. In addition to this, draft regulation do not designate subject product(s) and chemical(s), only state that DTSC will designate them later, and no one can evaluate benefit on the reduction of risk and expected cost of the draft regulation. As a result, validity and rationality of the draft regulation could not be evaluated.</p> <p>Considering international stream of commerce, there will be significant influence on the international society as wide spectrum of chemicals, including chemicals in the article (manufactured item)</p>	

		<p>will be regulated, validity and rationality of the draft regulation should be well verified, harmonized with and shared with stakeholders not only insider but also outsider of the state of California.</p> <p>Subject product(s) and chemical(s) should be clearly stated in the draft regulation, and at least, regulatory impact assessment under Executive Order of the United States 12991 should be proceeded, verified the validity and rationality of the draft regulation, then the result of the assessment should be placed on the public comment along with the draft regulation.</p> <p>Before going into the details, we would like to express several overarching comments. This is because this regulation is trying to introduce quite a new concept to the chemical management in products. Our industry would like to contribute to the society in the way all of us can safely use the products, however, on the other hand, we are also concerned with the potential confusion in the course of daily business or unnecessary burden to the society as a whole by introducing such new concept, neither of which may be welcome also from the environmental point of view, as potential supposedly duplicative work induced by such action may increase the environmental impact, not only limiting to the chemical management.</p> <p>Firstly, this concept is too different from other existing regulations such as in EU's RoHS and REACH (and WEEE, if including the recycling).</p> <p>In SAICM recommendation, international communications and the data buildings are commented (e.g. recommendation #105 or #129). We believe the purpose of such recommendation in SAICM is trying to avoid unnecessary activity and burden to each individual action</p>	
--	--	---	--

		<p>to build such information. We hope this regulation would find a way to utilize such information already established through other regulation or the knowledge built upon, such as through SIEF (Substance Information Exchange Forum) by EU REACH or to harmonize the way of restriction.</p> <p>Secondly, each of the processes to achieve the purpose of this regulation seems quite dependent on each company's individual work or the establishment of each of the processes. Even if we need to respect each company's liberty to create its own way of business as well as the research and development to find alternatives, if they are totally and individually done, the total environmental burden and its related social cost may increase, which we would definitely like to avoid.</p> <p>Thirdly, this program does not seem to pay enough attention to the confidentiality through supply chain activity. Most of the cases, the suppliers' or the purchasers' names are categorized as confidential business information, therefore, request for such information or any supposed action in this program would be hard to achieve. Such protection to the business confidentiality, including the supply chain information, is necessary for a healthy company activity, and we believe such healthy company activity will result in protecting consumers' liberty of selection in the long run.</p> <p>Lastly, we want the regulator to understand that the industries have been and will be trying hard to reduce the environmental impact related to chemicals, while trying to improve the performance of the products at a reasonable price. Therefore, to change to an alternative or to find an alternative chemical by the way it would fulfill the overall requirement would, in most cases, require drastic innovation in this field, which may take a long while. This can especially be seen in the field of advanced technology,</p>	
--	--	---	--

		<p>therefore such investigation may take like a decade till they would become usable in the society. We hope our comments above, together with below, would be taken into consideration before the finalization of this regulation. For your reference, the semiconductor industry, a part of electronics and information technology industries, is expressing its view to chemical management and potential regulations as found in the following URL. It is our pleasure that you would take your time to visit the site to have a look at the paper related to chemical management.</p> <p>http://www.semiconductorcouncil.org/wsc/agreements-white-papers</p> <p>After the visit, please click</p> <p>“WSC Essential Considerations for the Regulation of Chemicals Used in Semiconductor Manufacturing and Products - May 2012”</p>	
--	--	--	--

"Comment on specific item"

page	Clause/ Subclause	Comments	Proposed change
4	SS69501.1. Definition (6) “Adverse public health impacts”...	This definition here says the “Public health includes occupational health”. As this regulation takes care of “consumer products”, this definition to include “occupational health” does not sound adequate.	The sentence “Public health includes occupational health” should be deleted.
8	SS69501.1. Definition (18) “Certified assessor”...	Please see comments to Article 8.	
12	SS69501.1 Definition (52) “Reliable information”...	By the definition, “published” information is said to be “reliable”, however, in the field of chemicals, the final judgment of the hazard including its NOAEL would require a lot of disputes and discussions. Therefore, we do not think they are “reliable” only because they are published.	Instead, we suggest that DTSC should issue stakeholders’ consultation to such information or encourage stakeholders to establish Forum, like EU SIEF.

13	SS69501.1. Definition (60) “Trade secret”...	As written in the general comment, from daily business point of view, supply chain players’ name or the information given by those players are also considered to be a trade secret. Also, when considering the need to research or develop a new chemical or a new way of chemical application, they can be done not by the assembly companies but by chemical companies. It is not adequate for an assembly company to give the R&D plan of a chemical company; this would usually be a trade secret, which an assembly company cannot reach or does not have the right to disclose.	This definition should also include language like “Trade secret may also include the information which can be obtained through the daily course of business, such as, but not limited to, the name of the players in the supply chain or the information obtained through their activities in the supply chain, or the information which the responsible entity cannot obtain through the daily course of business.”
14	SS69501.2. Duty to Comply and Consequences of Non-Compliance.	The total lead-time through supply chain to produce a consumer product is, though each player trying hard to reduce it, quite long, and each portion of the supply chain is always keeping some amount of inventory at each stage.	The restriction to a product containing Chemical of Concern should consider sufficient time frame by balancing the time to allow to eliminate those inventory in a reasonable manner and the hazard caused by them. This is to avoid unnecessary disposal of materials and half-products, which may cause another kind of environmental impact.
14	SS69501.2. (b)(1)(B) / (C), (2)(A)	It is hard to understand why such information is required as “(B) the name of, and contact information...to whom the manufacturer or importer directly sold the product within the prior twelve (12) month;” or “retail sales outlets”. We have three points to this. 1) It is difficult to understand why such information is requested by DTSC. If such information is needed to the customers of a	We do not think it is practical to ask for such information.

		<p>responsible entity, the duty would have to be for the entity to inform such customers directly.</p> <p>2) There is no rationale to limit the time scale “within the prior twelve (12) months”, as the adverse effect may not vary by the time the product was sold.</p> <p>3) As written in “Trade secret”, usually the name of the players are trade secrets, therefore, they have to be granted as “trade secrets”.</p> <p>Also, due to this, any player further down the supply chain than the direct customer is, most of the cases, unknown to the player.</p>	
17	<p>SS69501.4. Chemical and Product Information (a)(3)/(4)</p>	<p>We have two concerns here.</p> <p>1) Availability of such information; This section mentions that DTSC would “ request a responsible entity or a chemical manufacturer” for the information, however, in many cases, such “chemical manufacturer” could be located outside California and may not have any direct sales in California. As written in the “trade secret”, their name may not even be known to any of the responsible entity, or the chemical manufacturers do not know that their products are eventually contained in the consumer products and sold in California. We wonder how such request for information from a chemical manufacturer is obtained.</p> <p>2) Only by reading this section, DTSC can ask for any information by the name that the information is needed for the review.</p>	<p>It is necessary to add some words to say that the requested information shall be only limited to the purpose for the review and DTSC should expressively give a basis why such information is requested and for which area of review such information is used.</p>

21	Article2. SS69502.2. Chemicals of Concern Identification.	We are concerned that the process to identify the Chemicals of Concern is quite dependent on DTSC's study and decision. At considering Chemicals of Concern, quite a lot of them are not scientifically proved to be hazardous, but concerned. In such a circumstance, each stakeholder should have each different opinion. Without receiving all of these opinions and holding discussions among them, the determination may not be considered fair.	
23	(b) Additions to the Chemicals of Concern List	We understand the importance of updating/adding the Chemicals of Concern to the list, however, we also would like to emphasize that such chemical information should also consider other regulations such as EU REACH. It would be burdensome for the industry if they need to take care of each of the regulations, which have the same kind of purpose worldwide and individually, therefore, we want this regulation to closely work with other countries'/areas' authority to take care of chemical controls, with the view to harmonize the approach.	
24	SS69502.3. Chemicals of Concern List. (c)(1)	As written in Article 2 Section 69502.2, some of the chemicals are not explicitly hazardous, and some do not have enough information either to say yes or no to such nomination. Under such situation, also considering such public comment information may not directly be aware by chemical manufacturers by the reason we mentioned in "Section 69501.2 Duty to Comply and Consequences of Non-Compliance., (b)(1)(B)/(C), (2)(A)", the public comment period (forty-five(45)days) sounds too short. We hope that the time frame like defined in EU REACH should be considered.	

25	<p>Article 3. Chemicals of Concern and Consumer Product Prioritization SS69503.2. Priority Products Prioritization Factors</p>	<p>Adding to California regulations, federal laws and international agreements, other major areas' (such as EU) regulation shall also be considered This is with the view to try to harmonize the scope or the chemicals in the list.</p>	
36	<p>Article 5. Alternatives Analysis (Comment 1)</p>	<p>The activity related to AA seems quite dependent onto each company's activity. It is understandable that each company has its right to research and develop by its own, but, on the other hand, the possible alternative chemicals to the same kind of products should be quite limited, therefore, each of those companies may come up with the same conclusion, sometimes with the report to say "no alternative". If they come up with such possible same kind of result, all of those various but the same activity multiplication seem wasteful both from social cost or environmental burden point of view. We want DTSC to consider establishing some kind of body like EU SIEF for AA activity either at Priority Product or Chemicals of Concern level, while each company can detain the right to individually investigate and report. At the same time DTSC should provide the information openly to those who need them, unless they are categorized as "trade secret", so that those who would perform AA activity could refer to some of the information.</p>	

36	Article 5. Alternatives Analysis (Comment 2)	In case of semiconductor industry, due to its advanced technology nature, the selection of a chemical takes a long research and development time, including the approval phase by the assembly product. Sometime, starting from the very first stage of selecting the potential alternative to actual first mass-production out, it takes like ten (10) to fifteen (15) years. The importance of reducing or elimination the Chemicals of Concern is fully understood by the industry, however, considering above, the time frame needed to switch to an alternative sometimes takes such time mentioned above. We hope that DTSC would understand such nature of the industry at considering AA activity.	
46	SS69505.5. Alternatives Analysis Reports. (d) Responsible Entity and Supply Chain Information.	As written in “trade secret”, the player’s information in the supply chain is a part of business confidential information. At the same time, the names of the further upstream or the downstream in the supply chain to a player than the direct supplier or the customer are not disclosed, therefore, such information cannot be provided.	This portion shall be deleted entirely.
52	Article 6. Regulatory Response SS69506. Regulatory Response Selection Principles. (b)(1)	Many companies selling consumer products in California have a headquarter function (to read such regulations) located outside of California. For them, to receive public consultation information may take time. Sometimes, it takes time to read English, when it is not their native tongue. Considering this, forty-five (45) days seems too short to comment.	The public comment period should be longer, such as sixty (60) days.

54	SS69506.4. Product Information for Consumers. (b)	We are concerned with the possible confusion related to the change management if the (b)(2)(A) is strongly required. We foresee that some of the products have some label while others do not under the same product name in the same sales area in the market at a changing time. That may confuse some of the consumers, while it is not practical to say that all the labels on the product package would be changed over a night.	We suggest that website or POP (point of purchase) card information at the shop should also be selected.
57	SS69506.8. End-of-Life Management Requirements.	This section seems to say that each company is requested that they not only fund but establish and maintain a management system to the end-of-life. We believe such system should be established mostly by the district government We understand that somebody should fund such activity, but the establishment and maintenance of its system is a different issue. This should cause chaos in end-of-life management, if each company tries to have its own and different system. We hope that such system should be considered as a part of waste management of California government, and through such study, funding method shall also be discussed.	We propose that EU WEEE method be studied.
61	SS69506.12. Regulatory Response Report and Notifications. (a)	As commented in the “trade secret”, manufacturers and importer, most of the cases, do not have the exact name of the retailers. Therefore, if such information is needed, this portion shall be rewritten to say that “a notice is sent to all direct customers of a responsible entity in the supply chain.” Considering this, if such information shall be given down to “retailers”, those direct customers should inform to their downstream, and as such. If so, some additions to the responsible players in the supply chain and their unique role need to be defined separately.	“The notice shall be sent to the retailers” shall be rewritten to “The notice is sent to all direct customers of a responsible entity in the supply chain.”

66	Article 8. Accreditation Bodies and Certified Assessors SS69508. Qualifications and Certification for Assessors. (a)	We are concerned that the assessors having the experience and knowledge described in (a) are really right people to do this assessment. As commented to Article 2., some chemicals are much difficult to determine if they should be put to the Chemicals of Concern.	We suggest that the assessors do not work individual bases, but such experts group are established and maintained By DTSC. In such way, the experience and knowledge should be accumulated.
75	Article 10. Trade Secret Protection SS69510. Assertion of a Claim of Trade Secret Protection.	The trade secret mentioned here seems too much onto the engineering and know-how issue. However, in the daily course of business, those information related to supply chain or the plan of R&D are confidential business information. Especially, the consumer product companies or its direct upstream companies are NOT mostly chemical manufacturers. Most of the cases, their names are unknown.	We request that the definition of trade secret shall be reconsidered to include those information. Also, from this point of view, we want DTSC to consider to limit requested information to minimum level to achieve the purpose of this regulation..

GCREgs@DTSC

From: Becky Klawans <hasklaws@mac.com>
Sent: Wednesday, October 10, 2012 9:09 PM
To: GCREgs@DTSC
Subject: Chemicals of Concern

Dear Department of Toxic Substances Control,

I am emailing you to express my support for the law passed in 2008 that requires the state to make a list of chemicals of concern, identify possible alternatives, and regulate the substances to reduce or eliminate public exposure. The public has a right to know what is in the products that they buy or are exposed to and to have them reduced and regulated. Research has shown that chemical substances leach out of plastics, fabrics, and other materials and people ingest them or absorb them through their skin, and that this is especially harmful to the unborn and children. Please regulate and remove toxic chemicals and chemicals of concern and end this type of toxic exposure.

Sincerely,
Becky Klawans



CORPORATE ENVIRONMENTAL EXCELLENCE

October 8, 2012

Krycia Von Burg, Regulations Coordinator
Regulations Section
Department of Toxic Substances Control
P.O. Box 806
Sacramento, CA 95812-0806

Via Mail and Email: gcregs@dtsc.ca.gov

Dear Ms. Von Burg:

On behalf of Koch Industries, Inc. (KII) and its affiliate companies, we appreciate this opportunity to comment on DTSC's Safer Consumer Products Proposed Regulations, R-2011-02 ("Proposed Regulations"). KII owns a diverse group of companies involved in refining and chemicals; process and pollution control equipment and technologies; minerals; fertilizers; polymers and fibers; commodity trading and services; and forest and consumer products. KII companies have a presence in nearly 60 countries with approximately 70,000 employees – over 1,400 of which are in California. KII has been working with the Green Chemistry Alliance (GCA) and several of our trade associations. KII supports the comments submitted on behalf of GCA, California Manufacturers & Technology Association, American Forest and Paper Association, American Cleaning Institute, American Wood Council, and Grocery Manufacturers Association ("Trade Association Comments") to DTSC on this important issue.

KII fully understands DTSC's desire to promulgate this new regulation as soon as possible. However, the Proposed Regulations as currently constructed are unworkable, fundamentally flawed and may not pass legal review. If DTSC continues to pursue the framework as laid out in the current version of the Proposed Regulations, the effective implementation could suffer major delays while these issues are addressed. Although we are providing our comments to DTSC on the Proposed Regulations as written, KII strongly encourages DTSC to focus on regulatory alternatives, such as the proposal submitted to DTSC by GCA on November 1, 2010, that have a greater chance of being implemented, passing legal review and achieving the stated objectives of the AB 1879. For the record a copy of that early proposal is available at: http://www.greenchemistryalliance.org/Media/DTSC_SCPA_GCA_Comment_Ltr20101101.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1.

Generally, the Proposed Regulations contain four major fundamental flaws that are discussed in more detail in the Trade Association Comments:

- a. **Lack of Clarity:** DTSC's reservation of unprecedented discretion in the decision making process and providing no criteria upon which the regulated industries can determine what DTSC may consider "safer" as a part of the alternatives analysis creates confusion and uncertainty for the regulated community. Based on the plain reading of the Proposed Regulation, there is no way for a regulated entity to understand what is

October 8, 2012

Page Two

- b. required, how to comply, and when or if in the process DTSC will make final determinations.
- c. Conflict with Existing Authorities and Laws: As described more fully in the Trade Association Comments, DTSC's Proposed Regulations are in conflict with existing occupational safety laws, EPA's chemical inventory and review process established by the Toxic Substances Control Act (TSCA), and the authorities provided to the U.S. Consumer Product Safety Commission under the Consumer Product Safety Improvement Act (CPSIA) of 2008. Associations have also pointed out in comments that the Proposed Regulations are in conflict with or attempt to supersede other authorities such as those provided under the Federal Food, Drug, and Cosmetic Act (FFDCA) to the Food and Drug Administration.
- d. Exceeding Authority Granted by Underlying Statute and Preemption: DTSC has exceeded the authority granted to it by the legislature in the drafting of the Proposed Regulations. There are several areas where DTSC has ignored the direction of the statute and gone beyond the authority granted, the Trade Association Comments provide further detail on these areas. In addition, federal law preempts certain aspects of the regulation. KII suggests that DTSC carefully review federal laws and possible preemption, whether express or implied, prior to finalizing the Proposed Regulations.
- e. Inappropriate Intrusion into the Business Decision Making Process, Loss of Proprietary Information, and Competitive Disadvantage: The Proposed Regulation provides for an unprecedented level of intrusion into the confidential business information ("CBI") of the Responsible Entity. One example is the requirement to provide unit margin and marketing information as part of the alternatives analysis. The margins and marketing of a product has no relation to the safety or environmental attributes of a chemical. Requiring the submission of irrelevant information is not only a waste of resources, but where this information will be shared allows for competitors to access sensitive information and benefit from the work, resources, time and knowledge of the first company to submit.
 - Information requests should be limited to that information essential to evaluating and communicating potential adverse public health and environmental impacts of the Chemicals of Concerns and Priority Products.
 - Requests for information concerning pricing, volume, margins, customer lists, supply chain information, manufacturing process information, etc. is unnecessary, inappropriate and could potentially raise anti-trust issues. These requests are made in the name of transparency when in reality they are unnecessary and do nothing to advance the stated purpose of the regulation, that being to provide safer consumer products to the citizens of California.

October 8, 2012

Page Three

- The collection and dissemination of this information in a public forum will stifle innovation and remove the incentives for pursuing new products and markets.
- DTSC should simply judge the output of their decision-making process concerning the products that the Responsible Entities wish to bring to market.
- Instead of DTSC, the Responsible Entity should be allowed to self-certify as companies currently do for many existing local, state and federal regulations.
- This intrusion into the Responsible Entity's CBI highlights DTSC's lack of understanding of the realities involved with making important business decisions. Examples of the decisions that seem to be ignored include determining which chemicals should be used in a product, identification of customer acceptance criteria, determining how much to sell a product for, identifying how to protect proprietary information, and figuring out how to communicate effectively with customers. All of these decisions and more are business decisions that can determine whether a product is successful in the marketplace; these are not decisions for DTSC to make.

The Trade Association Comments elaborate on these fundamental flaws and provide specific citations and examples to help DTSC understand why the Proposed Regulation has not met the requirements of the Administrative Procedures Act nor the California Environmental Quality Act. In addition, the Economic Impacts Analysis is inadequate as it failed to fully evaluate the economic impacts of the Proposed Regulations. The economic and fiscal analysis should be completed to include the true costs to California, consumers, and the regulated community.

KII supports and incorporates by reference the detailed Trade Association Comments submitted in response to DTSC's Proposed Regulations. KII encourages DTSC to continue to work with industry to develop workable, practical and legally defensible Proposed Regulations. Should you have any questions, KII would welcome the opportunity to provide further clarification. Please contact our California representative, Dawn Koepke (dkoepke@mchughgr.com, 916-930-1993) for further information.

Sincerely,



Pamela Beilke
Environmental Excellence Manager
KII EHS Excellence

GCREgs@DTSC

From: Sheila Lemons <sheila_lemons@att.net>
Sent: Wednesday, August 01, 2012 3:45 PM
To: GCREgs@DTSC
Subject: Reference Number R-2011-02

Categories: Comment

I am in favor of this bill: Reference Number R-2011-02

State should adopt proposed rules on toxic chemicals.

Thank you,

Sheila Lemons

Got art?

[SLFA Studio](#)

GCREgs@DTSC

From: Levitan, Lynn <LLevitan@crowell.com>
Sent: Friday, August 03, 2012 2:48 PM
To: GCREgs@DTSC
Subject: Preliminary List of Chemicals of Concern?

Ms. Von Burg:
Please advise if there is a preliminary list of Chemicals of Concern available for review.
Thank you,
Lynn

~~~~~

**Lynn R. Levitan**  
**Counsel**

**Crowell & Moring LLP**

515 South Flower Street - 40th Floor  
Los Angeles, CA 90071

 **General Office:** (213) 622-4750

 **Direct dial/voicemail:** (213) 443-5532

 **RightFax:** (213) 622-2690

 **E-mail:** [llevitan@crowell.com](mailto:llevitan@crowell.com)

<http://www.crowell.com/Professionals/Lynn-Levitan>

Washington, D.C. \* New York \* San Francisco \* Los Angeles \* Orange County \* Anchorage\* London\* Brussels

 Please consider the environment before printing this e-mail

Crowell & Moring LLP, Privileged and Confidential, Attorney-Client Communication, Attorney Work Product: This message contains privileged and confidential information. IF IT WAS SENT TO YOU BY MISTAKE, DO NOT READ IT. Instead, please notify the sender (or [postmaster@crowell.com](mailto:postmaster@crowell.com)) by reply e-mail, and delete this e-mail. Unauthorized dissemination, forwarding or copying of this e-mail is strictly prohibited.

=====

## GCREgs@DTSC

---

**From:** Robert Levy <robertmlevy@comcast.net>  
**Sent:** Monday, October 01, 2012 8:48 AM  
**To:** GCREgs@DTSC  
**Subject:** regulations

**Categories:** Comment

As a lawyer who has handled many cases over the years and unsuccessfully worked on trying to establish a cause of action arising from the fear of cancer, I can promise you that the only way to obviate fear is to have a government that acts independently of the pressure of the people who earn money from that which can and does harm us. Please do not back down. Impose stringent regulations for the identified chemicals and do not succumb to pressure from those whose interest is economic rather than that of the health and safety of the community. Thank You.

HAVE A GREAT DAY  
Robert Levy



## GCREgs@DTSC

---

**From:** Toni Littlejohn <toni@wild-carrots.com>  
**Sent:** Monday, October 01, 2012 10:17 PM  
**To:** GCREgs@DTSC  
**Subject:** On controlling toxic chemicals

Dear Dept of Toxic Substances Control of CA,

It is very important to the future of our state and country that you complete and implement regulations controlling toxic substances.

Thank you,

Toni Littlejohn



## GCREgs@DTSC

---

**From:** Nan Lorenzen <nhlorenzen@earthlink.net>  
**Sent:** Tuesday, October 02, 2012 10:00 PM  
**To:** GCREgs@DTSC  
**Subject:** please!

I know you are under hurricane pressure from the chemical industry to weaken the regulations for the 2008 law to protect our health and our environment.

Please, please listen to your conscience and fend off their pressure.

Remember, it is your health and that of your family in jeopardy as well as the rest of us.

Please care!

Thank you,

Nannette Lorenzen



## GCREgs@DTSC

---

**From:** Maggie Mahboubian <mmahboubian@roadrunner.com>  
**Sent:** Wednesday, October 10, 2012 12:51 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative

Dear Ms. Von Burg,

I am writing in response to the pending implementation of the Green Chemistry Regulations in the state of California. I have not been able to find a list of the Chemicals of Concern to understand if or how my company will be impacted. I make skincare using GRAS or edible grade ingredients. I also make natural perfumes using essential oils and other naturally derived extractions. Furthermore, the proposed regulations do not contain an exemption or consideration of any kind for small businesses like mine and which could potentially harm me and put me out of business entirely.

Cosmetics are already regulated by the FDA, although various states, including California have been adding legislation that may make it difficult for small, domestic manufacturers to make and sell their products not only in their own state, but across state lines. The FDA already has a list of chemicals that are not to be used. How will this regulation improve on the nationwide law that already exists and why should we have to pay to ensure a law that is already in effect. How will the Green Chemistry Regulations be enforced?

In this difficult economic climate can we afford to continue with over-regulation of an industry (like the cosmetics industry) that has a safe track record? I am a strong advocate of consumer safety, but unclear and over-regulation with the possibility of my not being able to finance the requirements will not make the industry safer. It will simply put me out of business and offer the public fewer alternatives.

Finally, the list is called "Chemicals of Concern", rather than chemicals that have been PROVEN to be toxic. There is a big difference in terms of the science. How can a regulation be formed on the basis of a "Concern"? Why waste taxpayer dollars on legislation that is not proven? I just don't understand this and it seems potentially harmful economically.

Thank you for your attention,  
Maggie Mahboubian

# MARIN COUNTY HAZARDOUS AND SOLID WASTE MANAGEMENT JOINT POWERS AUTHORITY

Belvedere:  
Vacant

October 10, 2012

Corte Madera:  
David Bracken

DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806

County of Marin:  
Matthew Hymel

Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Fairfax:  
Judy Anderson

**RE: Comments on Draft Regulations for Safer Consumer Product Alternatives**

Larkspur:  
Dan Schwarz

Dear Director Raphael:

Mill Valley:  
Jim McCann

The Marin County Hazardous and Solid Waste Joint Powers Authority is a supporter of the development of the Green Chemistry program as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

Novato:  
Michael Frank

Ross:  
Rob Braulik

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

San Anselmo:  
Debbie Stutsman

San Rafael:  
Nancy Mackle

Sausalito:  
Adam Politzer

While we generally support the proposed regulations, we request that you consider the following modifications:

Tiburon:  
Margaret Curran

(1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from the California Product Stewardship Council (CPSC) and local government agencies and the public prior to approving the plan.

(2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions:

Now is the time for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,



Michael Frost  
Executive Officer

Cc: JPA Board Members

*f:\waste\jpa\legislative support\dtsc green chemistry.docx*

**From:** Devi Peri <Devi.Peri@marinsanitary.com>  
**Sent:** Thursday, October 11, 2012 3:44 PM  
**To:** GCREgs@DTSC  
**Subject:** Green Chemistry program

October 11, 2012

DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806  
Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**RE: Comments on Draft Regulations for Safer Consumer Product Alternatives**

Dear Director Raphael:

Marin Sanitary Service has long been a supporter of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,

Devi Peri  
Education Coordinator  
Marin Sanitary Service

**Devi Peri**

**Education Coordinator**

*Marin Sanitary Service*

*Marin Recycling and Resource Recovery*

535 Jacoby Street

San Rafael, CA 94901

**415-458-5539**

**Let's make Marin a Zero Waste zone by 2025.**

**Visit [www.zerowastemarin.org](http://www.zerowastemarin.org) to find out how you can help!**

10 October 2012

Debbie Raphael, Director  
Department of Toxic Substances Control  
State of California  
PO Box 806  
Sacramento, CA

Re: Public Comments on the Safer Consumer Product Regulations

Dear Director Raphael,

Thank you for the opportunity to comment on the proposed Safer Consumer Product Regulations. It has been a pleasure to work with you and your staff in the development of these requirements. I thank you for the time, effort, and dedication the staff has put into listening to all of the stakeholders and the hard work it has taken to put together the drafts and revisions for this groundbreaking new step in protecting public health and the environment from chemicals of concern in consumer products.

I strongly support the goals and objectives of AB 1879 and the requirements outlined in the Safer Consumer Product regulations. Overall, I think the department has done an excellent job of balancing the needs and interests of a variety of stakeholders. Rather than addressing the regulations line by line, I have confined my comments to a few key conceptual areas. These comments are offered, not as a criticism of the excellent work done by the department, but as suggestions in the interest of providing additional information and perspective to help achieve better clarity, efficiency, and effectiveness in implementing this important program.

### **Comments—**

**AB 1879:** This bill requires the department to establish (1) a process by which chemicals or chemical ingredients in products may be identified and **prioritized** for consideration as being chemicals of concern; and (2) a process by which chemicals of concern in products and their potential alternatives are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. The chemical identification and prioritization process shall include the following factors—volume in state commerce, the **potential for exposure** in a consumer product, and the **potential effects** on sensitive subpopulations. It shall reference and use to the maximum extent feasible, but not be **limited to using only**, the available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes.

There are three very important points I would like to make from this bill—first, the required processes build upon, rather than copy, the concepts and requirements and defined by other government entities. It is my opinion that if the legislative intent were merely to implement the existing chemical regulations from the EU, other countries, or states, then the most expedient way to do so would have been to cite those existing laws. Instead, the authors of this bill chose to move forward the principles of green chemistry through a mandate to the department to

determine how best to limit exposures to and/or reduce the level of hazard from chemicals of concern in consumer products.

I believe, based on the observable impacts on public health and the environment from the use of chemicals today, that current regulatory requirements and methods are not sufficient to adequately control the unnecessary releases of and exposures to all potentially harmful chemicals over the life cycle of consumer products. I, therefore, firmly support the goals of AB 1879 and the intent (if not all of the details) of the new proposed safer consumer products regulations, including establishing lower regulatory thresholds where appropriate, to protect occupational and public health from the use of chemicals of concern in consumer products.

The second point I would like to make is that the bill clearly requires the identification and **prioritization** of chemicals of concern. I believe that one of the biggest weaknesses of the proposed regulations is skipping the very important step of prioritizing the chemicals of concern before going directly to prioritizing products. Similar chemical prioritization processes by other nations (EU, Canada) and governments (state laws for the protection of children from chemicals of concern) have identified a shorter list of priority chemicals based on the severity of known hazards. This enables them to start with the highest concerns, solicit information from manufactures about the products that use these chemicals, and evaluate the potential releases, critical exposure pathways, and potential risks in a systematic manner before listing priority products for immediate evaluation. I believe that adding a process for prioritizing chemicals will refocus the regulations on **chemicals of concern** in priority products and enable much better selection of priority products to evaluate in the next few months and years.

And the third point is the identification and prioritization of chemicals shall, by law, consider potential exposures and effects, not proven exposures and effects. There has been a shift in the development of the regulations that has moved towards proven rather than potential harm. I think this is a very important distinction—knowledge and understanding of chemical hazard traits and behavior should be sufficient warning to list and prioritize the chemicals of concern for consideration and to develop response measures to protect human health and the environment.

***Chemicals of concern list:*** The chemicals of concern are derived from a list of lists—chemicals with specific hazard traits and toxicological endpoints listed by authoritative bodies. This is a great place to start, if not a comprehensive list of all the important lists of known hazard traits. Chemicals that cause sensitization should be part of the list.

There is much overlap between these lists but all of these chemicals are known to be potentially harmful. The factors listed for adding chemicals to the list of chemicals of concern are also good; however, I do not believe that the Department should consider the availability of a safer alternative in determining whether to list a chemical as a chemical of concern. Other mitigation measures and responses may be necessary and appropriate in cases where there are no current substitutes available.

**Threshold:** I fully support the concept, included in the informal draft regulations but eliminated in the proposed regulations, of establishing **by rule** a default AA threshold, of 0.01% by weight (100 ppm) that can be adjusted up or down as appropriate based on the potential adverse impacts of a specific chemical. This is solid concept and a reasonable, if not proven, default value. This value is consistent with the more stringent substance restriction we see for cadmium in many RoHS countries, with the concentration ranges we calculate from Proposition 65 safe harbor levels, and is about the middle of the range we typically see for children's product restrictions. I believe there is precedent in international regulations for establishing a default value that is generally protective for the intended purpose of the rule without demonstrating that the selected value is the most appropriate value for every chemical in every situation.

However, I think it important to note that any adjustment up or down of the rule default should be based on a solid assessment of the available data on the potential risk to humans and the environment. In other words, the burden of proof should move to the department when making technical adjustments to the default threshold outside of the rulemaking process.

Likewise, a very specific chemical of concern—priority product pairing threshold identified outside the open rulemaking process would need to be based on sufficient information to indicate a real potential for adverse impacts above the proposed threshold level. In my opinion, this means the department would need to conduct a chemical-specific priority product risk evaluation through an open, public process, with sufficient review times to provide opportunity for stakeholder and public input, review, comment, and debate before finalizing the threshold. While this may actually provide the best method of determining an appropriate level for a specific chemical of concern—priority product pairing where the potential for harm is great enough that the cost of an AA is justified, this will move much of the debate to the front end of the process and my concern is that this debate is likely to substantially bog down the entire AA process and delay the AA process and regulatory responses needed to reduce the hazard and exposures to chemicals of concerns.

And finally on the topic of thresholds, I will briefly comment on what has been touted as a worldwide “harmonization” of a chemical *de minimis* threshold at 0.1% (1000 ppm). Chemical action thresholds, whether for reporting, labeling, or material restrictions, vary widely depending on both the nature of the substances and the purpose of the regulation. There are many, many examples, the clearest of which is reporting for REACH SVHC at 0.1% by weight in articles vs Canada CMP reporting that is based on 100 kg total substance imported or used by a single manufacturer at any concentration in any given product or component. The latter total number can be adjusted up or down.

Bottom line—the AA threshold should be established to accomplish the purpose of this law—to protect public and the environment—a concentration below which there is no need to further consider limiting exposure throughout the product life cycle, regardless of whether the chemical of concern is added as an intentional ingredient or present as a contaminant in the raw or recycled materials, processing agents, intermediates, air, or water used in the manufacturing process.

**Cumulative:** Adverse impacts on public health and the environment are rarely confined solely to exposure to a single chemical. Any assessment of chemicals of concern in a product needs to at least consider the potential cumulative effect of exposure to more than one chemical of concern exhibiting the same hazard trait. While comprehensive risk assessment is more complicated than the simple addition of concentrations of substances with the same hazard trait, there is precedent for this type of evaluation in the EU labeling requirements for chemical mixtures. In the absence of moving towards full comprehensive risk assessment per se, the surrogate of adding together the concentrations of multiple chemicals of concern with the same hazard trait is a reasonable approximation (although it should be noted that additive does not take into account synergistic effects) for determining whether the product meets the AA threshold exemption requirements.

**Demonstration for AA threshold exemption:** The proposed regulation is not clear about what data are required to substantiate the presence or absence and the concentration of chemicals of concern in the priority product when applying for an AA threshold exemption. It is also not clear what happens if the priority product contains other chemicals of concern exhibiting the same hazard trait as those included as the basis of listing the priority product but which are not well known and, therefore, not included in the priority product listing.

I suggest that knowledge of materials and processes are only adequate as substantiation of the presence or absence and concentration of all chemicals of concern as long as the entire manufacturing process is under the direct control of the responsible entity. The more complicated the product and the more distant the suppliers and manufacturers of materials, ingredients, components, and final assembly of manufactured and formulated products, the more analytical data that should be required to fully substantiate that the AA threshold exemption has been met. I believe the department needs not only to place the burden of proof on the responsible entity but also needs to provide in the rule, the minimum requirements for documentation that the threshold exemption has been met. The department should specify appropriate practical quantitation limits for the chemicals and materials, components, or products specified in priority product listing. This provides certainty for the companies claiming an exemption and ensures uniform implementation across an industry sector.

I support the threshold exemption notification process as a necessary step for ensuring the absence of chemicals of concern in a listed priority product and I think that each exemption notification packet should be available on the web in redacted form with sufficient time for technical review and public comment.

**Chemicals of concern in priority products:** Somewhere in the writing and rewriting of this regulation, the written focus of the AA process and regulatory responses seems to have shifted from evaluation of the alternatives to the **chemicals of concern in priority products** to evaluating alternatives to priority products. Although I do not think this is what the rule is meant to imply, the text of the rule needs to be very clear that this is about defining alternatives for safer chemical selection and minimizing the potential releases and exposures for chemicals of concern throughout the life cycle.

***Practical and implementable:***

The factors outlined in the rule for selecting products and the elements that must be considered in conducting an AA are a reasonable starting point but the actual process for achieving these endpoints is either not laid out well or it is very muddled. Telling us what you want done (chemicals and products) and what outcome needs to be achieved are far better than getting into a regulatory driven but piecemeal process just for the sake of process. My growing fear is that with each later iteration of the rule, the more you specify and the more you drive towards a cookie cutter approach, the less you will actually achieve in real outcomes.

I am sorry but I do not believe that a whole bunch (i.e., 10 chemical-component pairings on a durable product in three years) of piecemeal product AAs are efficient or effective, let alone implementable. My belief is that for the most part, one AA per product per five-year period that considers multiple chemicals of concern of, when appropriate, more than one hazard trait and more than one component would be a more reasonable approach. The obvious exception to this rule of thumb would be to conduct single component AAs for widespread use of relatively standard components that are used in many types of products (e.g., power cords).

By contrast to the piecemeal approach, I would offer the example of RoHS legislation. RoHS required manufacturers to look at the entire product use of specified substances and determine where there were viable alternatives and where viable alternatives were going to take a substantial amount of time to develop (exemptions). This was a lengthy process that required the knowledge and expertise not only of the manufacturers of products but of the whole supply chain that served the electrical and electronic product industry. I believe the RoHS approach is more similar to the discussions I have heard on implementing green chemistry principles—start with the assay of a product and define the scope of the green chemistry challenge and begin there—than it is to relying on randomly picking and choosing chemicals in certain components of a product. Although pieces are important, the application of green chemistry principles is about the whole. This feels like we have lost the holistic approach between last fall and this newer set of proposed regulations.

The obvious question is—does the department really have the knowledge and expertise on product design, materials, and components of every consumer product that may contain chemicals of concern that they feel comfortable with picking and choosing chemicals of concern in materials and components rather than asking the manufacturers take a systematic look at the product and propose an AA plan that describes how to achieve the best outcome for the resources expended?

***Processes and assessors:*** The department has been pushed time and again to more clearly define processes under the guise of promoting certainty for responsible entities that the notifications and reports they produce will meet the requirements. I believe certainty in the AA process comes from achieving and clearly demonstrating the desired outcomes, not from checking the boxes in a meaningless process or blindly applying models, scoring, and checklists. Analytical tools are just that, they provide data for comparison and analysis but not implementable alternatives or definitive answers.

I would contend that the AA team must have a clear understanding of product design, function, materials, product construction and manufacturing processes. These product experts must be closely coupled with environmental experts who can analyze the alternatives within the context of the principles of chemical behavior, release and transport, exposure assessment, toxicology, and life cycle environmental impact analyses.

“Those that lack knowledge and understanding frequently attempt to substitute hard process for creative thinking and expert judgment, with little regard for whether or not that process can actually achieve the desired outcome.”

This law and regulation requires a complicated scientific exercise, focused directly on achieving a very important outcome—protecting public health and the environment by determining the best way to limit exposure to and reduce the hazard posed by chemicals of concern. The AAs and regulatory responses produced under these rules will only achieve the desired outcome through the application of good science, innovative thinking, and the use of expert judgment. None of the outcomes will be enhanced from the development of elaborately laid out processes or the certification of assessors. Understanding the principles, factors, and criteria for consideration specified by the department and weaving them into the identification and analysis of alternative chemicals and actions that can be fully assessed is a better path. In other words, with an endpoint in mind, the technical experts can use their knowledge and experience to most efficiently and effectively achieve the goal.

An open process, systematic technical peer review, and encouraging public participation and comment are imperative to maintaining a level playing field across industry and ensuring quality analyses.

***Trade secrets and disclosure:*** I believe that the entire AA process needs to be as open and transparent as possible but without divulging truly competitive trade secret information. Full disclosure is a desirable endpoint; unfortunately, it is not yet a likely outcome. I think this is a situation where the carrot is likely to work better than a hammer—perhaps some kind of an incentive system that encourages full disclosure of chemicals of concern but I am not quite sure how such a system could be implemented. I would love to see the department think about an incentive for disclosure before the next revisions to the rule.

Thank you for listening.

Best regards,

Marjorie MartzEmerson

## GCREgs@DTSC

---

**From:** Cameron McKinley <cammckinley@mac.com>  
**Sent:** Monday, October 01, 2012 9:23 AM  
**To:** GCREgs@DTSC  
**Subject:** Protect consumers from dangerous chemicals

**Categories:** Comment

Dear Dept. of Toxic Substances Control,

PLEASE finish writing regulations to protect citizens from harmful toxic chemicals, and then enact those regulations. Please do it for your own health, your family's health, my family's health and the health of everyone.

Cameron McKinley  


## GCREgs@DTSC

---

**From:** sun goddess... <shetaz711@yahoo.com>  
**Sent:** Tuesday, October 09, 2012 10:58 AM  
**To:** GCREgs@DTSC  
**Subject:** COC

**Categories:** Comment

Ms. Von Burg:

Why are you trying to adopt a new legislation about Chemicals of Concern when we (small businesses) haven't even seen a list of the chemicals you want on that list? Isn't that unfair to us? Living in California all my life, I now feel like this state has become run under a dictatorship. It's very sad what California is now turning into and many people are looking to move out and take their business with them.

I'm trying to open a very small business of my own making soap and bath products. I use a glycerin base for my melt and pour that I buy from another company. I don't make this soap, it's easier to buy a 25 lb block and use as needed. I also make cold process which is used with oils (palm, coconut, olive, avocado, canola) and lye. This soap is required to 'rest' for 4-6 weeks to cure. I use it myself and have never had a problem. Lotion, bath salts/scrubs, sugar scrubs and bath bombs:

Lotion is bought as a base product and fragrance is added.

Salt is a dead sea salt and fragrance is added.

Sugar is a raw sugar that is bought in a grocery store with oil (sunflower) and fragrance added.

Bath Bomb is a combination of citric acid and baking soda, small amount of fragrance and color added.

I've never bought a product for my soaps/bath products that have ever had a 'caution' sign by the name saying it could cause cancer or could potentially be dangerous to the public. That's not what I want.

Can you please send a list of what you consider COC in soap products? If you determine lye is one of those chemicals, you will be shutting down every person who makes soap. Lye is a critical ingredient since the discovery of soap from our ancestors.

Thank you,

Robyn McMullin

## GCREgs@DTSC

---

**From:** roger mendelson <rbmendel@aol.com>  
**Sent:** Thursday, October 11, 2012 7:56 AM  
**To:** GCREgs@DTSC  
**Cc:** LONI LONI HANCOCK; Gov@govmail.ca.gov  
**Subject:** control and exclude CHEMICALs OF CONCERN

to State Dept of Toxic Substance Control

we're all very worried about toxins in the environment--especially for kids and grandkids. Specifically BPA, Lead, phthalates, and many others.

Stand up to the chemical lobbies and protect people in California and USA.

We're watching you.

Roger Mendelson  
Monique Mendelson  
Adam Mendelson  
Laura Mendelson Stritzel





October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the Metal Finishing Association of Northern California [MFANC], the Metal Finishing Association of San Diego [MFASD], and the Metal Finishing Association of Southern California [MFASC], I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

MFANC, MFASD, and MFASC are nonprofit trade associations of management executives in the fields of metal finishing, electroplating, powder coatings, solar cell manufacturing, anodizing, polishing, decorative plating on plastics, optical coatings and related processes. These are essential components of California's high-tech industries, supplying surface treatments for electronics, aerospace and consumer goods.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

However, we remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

The most concerning aspect of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is

compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on exposure and hazard, and it must avoid duplication and conflicting regulatory requirements.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, the department predicts a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports this two-step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

We appreciate your consideration of our concerns. For further information or questions, please contact me at (310) 901-7745. Thank you.

Sincerely,

*Dan Cunningham*

Dan Cunningham,  
MFANC, MFASC, and MFASD Executive Director  
PO Box 6547  
Burbank CA 91510-6547

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

## GCREgs@DTSC

---

**From:** Amy Meyer <a7w2m@earthlink.net>  
**Sent:** Monday, October 01, 2012 1:29 PM  
**To:** GCREgs@DTSC  
**Subject:** chemicals in consumer products

Please require the state to do what the SF Chronicle called for this morning: **make a list of "chemicals of concern," identify possible alternatives, and regulate the substances to reduce or eliminate public exposure to them.** Everyone will benefit, including the head-in-the-sand sales force of the chemical industry.

Amy Meyer  


**From:** Richard Mezzavilla [<mailto:mez@astound.net>]  
**Sent:** Monday, October 01, 2012 5:23 PM  
**To:** Algazi, Andre@DTSC  
**Subject:** chemicals of concern

Dear Mr. Algazi,

It is my understanding that it will be the task of your department to finish writing the regulations having to do with substances that are on the list of "chemicals of concern" and that after having done so, the department will enact them.

It goes without saying that the health of all Californians is at stake in this matter. I sincerely hope that our state officials have not succumbed to the hordes of lobbyists that have been unleashed on them by the chemical industry.

I urge you and your department colleagues to write the most strident set of regulations that you can. The yet to be born citizens of our great state will someday join with us, the living, in offering all of you our deepest thanks in the future.

Sincerely yours,  
Richard A. Mezzavilla  
Walnut Creek, CA

## GCREgs@DTSC

---

**From:** njmichelli <njmichelli@att.net>  
**Sent:** Monday, August 20, 2012 12:01 PM  
**To:** Von Burg, Krysia@DTSC  
**Subject:** RE: Safer Consumer Product Rulemaking

Hi Krysia,

Thank you. I appreciate your prompt response. I'm trying to sort through how the "trade secret" part of the proposal will work. But it's still a bit confusing for me. Is there anyone that I could contact for clarification on that?

Thank you again,

Nancy Michelli

[REDACTED]

Email: [njmichelli@att.net](mailto:njmichelli@att.net)

[REDACTED]

---

**From:** Von Burg, Krysia@DTSC [<mailto:Krysia.VonBurg@dtsc.ca.gov>]  
**Sent:** Monday, August 20, 2012 11:31 AM  
**To:** [njmichelli@att.net](mailto:njmichelli@att.net)  
**Subject:** Safer Consumer Product Rulemaking

Hi Nancy,

Thanks for the voicemail. If you would like your comment to be considered for the Safer Consumer Product proposed regulations which were published in July 2012, then you will need to submit a new comment.

Please see the following link for all regulatory documents:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm> or <http://www.dtsc.ca.gov/SCPRegulations.cfm>

Thanks,

*Krysia Von Burg*

Office of Policy

Department of Toxic Substances Control

Tel: (916) 324-2810

[krysia.vonburg@dtsc.ca.gov](mailto:krysia.vonburg@dtsc.ca.gov)

## GCREgs@DTSC

---

**From:** Adit Mikaily <aditmikaily@hotmail.com>  
**Sent:** Wednesday, October 10, 2012 12:23 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative - Proposed Regulations

Dear Green Chemistry Regs DTSC,

I wish to express my viewpoint on the proposed Green Chemistry Regulations. As far as your "green" initiative is concerned, I am convinced that the only thing "green" about your initiative is the money that you foresee and anticipate going into your pocket!

Sincerely,

Adit Mikaily



## GCREgs@DTSC

---

**From:** Montgomery, John D <monty@te.com>  
**Sent:** Tuesday, August 07, 2012 5:55 AM  
**To:** GCREgs@DTSC  
**Subject:** Safer Consumer Products Regulations

**Categories:** Question

Where might one find the list of the 1200+ substances that California will focus on with the SCP Reg's.....?

**John D. Montgomery**

**Monty**

Manager - Product Environmental Compliance

  
[monty@TE.com](mailto:monty@TE.com)

## GCREgs@DTSC

---

**From:** Montgomery, John D <monty@te.com>  
**Sent:** Thursday, August 09, 2012 1:58 PM  
**To:** GCREgs@DTSC  
**Subject:** RE: Safer Consumer Products Regulations  
**Attachments:** COC-lists-weblinks2[1].pdf

So if I researched each of the websites on your Proposed Chemicals Lists document, I would come up with the 1200 substances?  
(re.: attachment)

Monty

---

**From:** GCREgs@DTSC [<mailto:GCREgs@dtsc.ca.gov>]  
**Sent:** Thursday, August 09, 2012 3:57 PM  
**To:** Montgomery, John D  
**Subject:** RE: Safer Consumer Products Regulations

Hi John,

Please see our website as we have posted information regarding the List of Chemicals of Concern,  
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm>

Kind Regards,

Office of Policy  
DTSC

---

**From:** Montgomery, John D [<mailto:monty@te.com>]  
**Sent:** Tuesday, August 07, 2012 5:55 AM  
**To:** GCREgs@DTSC  
**Subject:** Safer Consumer Products Regulations

Where might one find the list of the 1200+ substances that California will focus on with the SCP Reg's.....?

**John D. Montgomery**  
**Monty**

Manager - Product Environmental Compliance  
(717) 986-3139 tel  
(717) 877-1799 mobile  
(717) 986-7042 fax  
[monty@TE.com](mailto:monty@TE.com)

**Marcella Moran**

---

**From:** Marcella Moran <marcella@alohasantacruz.com>  
**Sent:** Wednesday, September 19, 2012 11:36 AM  
**To:** 'green.chemistry@dtsc.ca.gov'  
**Subject:** Green Chemistry Concern

*This email address  
does not work.*

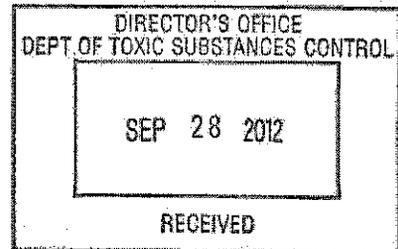
Hello,

My family runs and operates a small retail business in California. I recently attended a large resort tradeshow in Las Vegas where I typically begin to place orders for our upcoming Spring and Summer Seasons. Not a single vendor that I spoke to at this trade show had heard about "Green Chemistry" or the proposed changes. Many of the companies are based out of California. It leaves me feeling very uneasy. If the vendors are unaware of the law changes that may soon take place how can I as a retailer be confident that the merchandise I am buying will be compliant? What has been done to spread the word of the changes to Importers and vendors. If I cannot confidently purchase safe merchandise how can I operate my business and be compliant with the law? I do not think that small business such as our should be held liable for merchandise that is not compliant with these laws. It is not economically feasible for me to test products. I do not want to carry products that are not safe but I cannot economically or efficiently get the information I need to make that determination. The vendor should be required to know whether or not their product is compliant before they are selling it. If the vendor has a product that is suddenly not compliant the retailer should not have to suddenly shoulder that loss. If I have to buy merchandise now to operate my business and in 6 months if it is deemed unsafe what do I do? I cannot afford to shoulder that kind of loss but I also can't afford to not have merchandise for our stores.

1. Please consider providing better communication about these proposed changes to small business and vendors.
2. Please consider the crushing impact this law could potentially have on small retailers. Disney and Walmart sized corporations can afford lawyers and teams of staff to analyze product safety. The average small business cannot and has to rely on the vendor's word.
3. If a product is deemed unsafe please provide the retailer with time to move through the product or if they are not allowed to sell the product provide retailer's with a form of recourse against the vendor (for example the right to return unsafe product).
4. Small retailers should not be held liable for carrying unsafe products unless it can be shown that the product was deemed unsafe and they knew the product was unsafe at the time of ordering.

Thank you for reading my concerns.

Marcella Moran



All visitors are required to sign in prior to attending any meeting at the Visitor and Environmental Services Center, located just inside and to the left of the building's public entrance. Please allow adequate time to sign in and receive a visitor badge before the public hearing begins.

**Notice to Hearing Impaired - Accessibility.** If you have special accommodation or language needs, please contact Reasonable Accommodation Coordinator Adrian Recio, at (916) 324-3095 or by e-mail at [ARecio@dtsc.ca.gov](mailto:ARecio@dtsc.ca.gov) as soon as you read this document. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

## AUTHORITY AND REFERENCE

### Authority

These regulations are being adopted under the following authorities:

Health and Safety Code section 25252: This section authorizes and requires the Department of Toxic Substances Control (DTSC) to adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern. This section directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. This section also directs DTSC to reference and use available information from various sources, but does not limit DTSC to referencing and using only this information.

Health and Safety Code section 25253: This section authorizes and requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that take into consideration, at a minimum, thirteen (13) specified factors. This section also requires that the regulations specify the range of regulatory responses that DTSC may make following the completion of an alternatives analysis, including, but not limited to, eight (8) specified responses and "any other outcome the department [DTSC] determines accomplishes the purposes of [article 14 of the statutes]".

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991.) This section grants DTSC authority to adopt regulations to execute its duties.

### Reference

These regulations implement, interpret, or make specific the following statutes:

Health and Safety Code sections 25251, 25252, 25253, 25257, and 25257.1.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

### **Policy Statement Overview**

#### Background

There are currently more than 80,000 chemicals approved under federal law for use in the United States (U.S.). Each day, a total of 42 billion pounds of chemical substances are produced or imported in the U.S. for commercial and industrial uses. An additional 1,000 new chemicals are introduced into commerce each year.

Approximately one new chemical comes to market every 2.6 seconds, and global chemical production is projected to double every 25 years. The average U.S. consumer today comes into contact with 100 chemicals per day. In 2009, the U.S. Centers for Disease Control and Prevention released the Fourth National Report on Human Exposure to Environmental Chemicals, which measured 212 chemicals in the blood and urine of a representative population of the United States. The 2009 Report was updated in February, 2012 to include updated tables for 66 chemicals and tables for 34 new chemicals. California consumers and businesses are becoming increasingly aware and concerned about the abundance of chemicals that they are exposed to in the products that they use on a day-to-day basis in their homes and in the workplace.

For more than a decade, the California Legislature has considered nearly a hundred bills proposing chemical bans and broader chemical policies for California, heard testimony from "battling scientists" and was interested in developing a broader, more comprehensive approach to chemicals policy.

In 2003, the Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials commissioned a report from the University of California (U.C.) to investigate the current legal and regulatory structure for chemical substances and to report on how a California chemicals policy could address environmental and health concerns about chemical toxicity, build a long-term capacity to improve the design and use of chemicals, and understand the implications of European policy on the California chemical market.

In 2006, authors from U.C. Berkeley presented the commissioned report, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation* and made a connection between weaknesses in federal policy, namely the Toxic Substances Control Act (TSCA), and the health and environmental damage happening in California. The report broadly summarized their findings into what they called the "three gaps":

- *Data Gap*: There is a lack of information on which chemicals are safe and which are toxic, and what chemicals are in products. The lack of access to chemical data creates an unequal marketplace. California businesses cannot choose and make safer products and respond to consumer demand without ingredient disclosure and safety testing.
- *Safety Gap*: Government agencies do not have the legal tools or information to prioritize chemical hazards. Under TSCA, only 5 chemicals out of 83,000 have been banned since 1976. The California Legislature has frequently addressed this problem by approving individual chemical bans. Chemical bans come before the Legislature because there are very few other mechanisms in place at the federal or State level that can remove harmful chemicals from the marketplace.
- *Technology Gap*: There is an absence of regulatory incentive and market motivation which stems from the data gap, and a lack of educational emphasis on green chemistry methodologies and technologies. In order to build a substantial green chemistry infrastructure, a coincident investment and commitment must be made to strengthen industrial and academic research and development.

In 2007, the California Environmental Protection Agency launched *California's Green Chemistry Initiative* within DTSC. The *California Green Chemistry Initiative Final Report* released in December 2008 included the following six policy recommendations for implementing this comprehensive program in order to foster a new era in the design of a new consumer products economy, which includes inventing, manufacturing and using toxic-free, sustainable products.

1. Expand Pollution Prevention and product stewardship programs to more business sectors to focus on prevention rather than simple source reduction or waste controls.

2. Develop Green Chemistry Workforce Education and Training, Research and Development and Technology Transfer through new and existing educational program and public/private partnerships.
3. Create an Online Product Ingredient Network to disclose chemical ingredients for products sold in California, while protecting trade secrets.
4. Create an Online Toxics Clearinghouse, an online database providing data on chemical, toxicity and hazard traits to the market place and public.
5. Accelerate the Quest for Safer Products, creating a systematic, science-based process to evaluate chemicals of concern and identify safer alternatives to ensure product safety.
6. Move Toward a Cradle-to-Cradle Economy to leverage market forces to produce products that are "benign-by-design", in part, by establishing a California Green Products Registry to develop green metrics and tools for a range of consumer products and encourage their use by businesses.

In 2008, Assembly Bill 1879 (Chapter 559, Feuer) and Senate Bill 509 (Chapter 560, Simitian), were signed into law by Governor Schwarzenegger to implement two key recommendations of the *California Green Chemistry Initiative Final Report*: acceleration of the quest for safer products, and creation of an online toxics clearinghouse - recommendations #4 and #5 above.

#### Broad Objectives

The proposed regulations that are the subject of this notice, and the authorizing statutes (Health and Safety Code sections 25252 and 25253), are intended to implement recommendation #5 of the *California Green Chemistry Initiative Final Report* - Accelerate the Quest for Safer Products, and, thus, create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.

#### Specific Objectives

The specific objectives of the proposed regulations are to:

- Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.
- Establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by chemicals of concern.
- Specify the range of regulatory responses that DTSC may take following the completion of the alternatives analysis.

#### Proposed Regulations

The proposed regulations would add a new chapter 55, Safer Consumer Products, to division 4.5 of Title 22, California Code of Regulations. These regulations are necessary to satisfy the mandates of Health and Safety Code sections 25252 and 25253, which require DTSC to adopt regulations to establish a process to identify and evaluate chemicals of concern in consumer products and identify safer alternatives, and to specify regulatory responses that may be imposed upon completion of the alternatives analysis process.

#### Benefits

The proposed regulations are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and are viewed as a potential national model for chemicals policy reform. The rulemaking is a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water and a safer workplace. The rulemaking also promotes transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

### Relation to Existing State Regulations

The proposed regulation is not inconsistent or incompatible with any existing state regulations. An automated search of Titles 19 and 22 using the following keywords: "consumer products", "chemicals in consumer products", and "chemicals in commerce", was conducted via Westlaw and yielded no conflicting state regulations. In addition, DTSC worked with the Office of Environmental Health Hazard Assessment (OEHHA), the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies.

### I. Summary of Regulations

#### **A. Four-Step Process** [Section 69501(a)]

The regulations provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives:

- DTSC - The regulations establish an immediate list of Chemicals of Concern (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Chemicals of Concern (COCs).\* [Article 2, see section II for further details.]
- DTSC - The regulations require DTSC to evaluate and prioritize product/COC combinations to develop a list of "Priority Products" for which an alternatives analysis must be conducted. [Article 3, see section II for further details.]
- Product Manufacturers - The regulations require responsible entities (manufacturers, importers, and retailers) to notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. Manufacturers (or other responsible entities) for a product listed as a Priority Product must perform an alternatives analysis (AA) for the product and the Chemicals of Concern in the product to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the Chemicals of Concern in the product. [Article 5, see section III for further details.]
- DTSC - The regulations require DTSC to identify and impose regulatory responses to effectively prevent or limit adverse public health and/or environmental impacts, if any, posed by the Priority Product/Chemical of Concern (if the manufacturer decides to retain the Priority Product), or the adverse impacts posed by the alternative chemical/product selected to replace the Priority Product. [Article 6, see section IV for further details.]

#### **B. Applicability** [Section 69501(b)]

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, and are sold, offered for sale, distributed, supplied, or manufactured in California. The regulations do not apply to the following products:

(1) Products exempted by law (Health and Safety Code section 25251): dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices; food; and pesticides. The regulations also do not apply to products used solely to manufacture a product exempted by law.

(2) Products manufactured or stored in, or transported through, California solely for use out-of-state.

### **C. Responsibility for Compliance**

(1) The regulations [Section 69501.1(a)(54)] define "responsible entity" to include:

(i) The manufacturer (i.e., the person that makes the product or the person who controls the specifications and design of, or use of materials in, the product).

(ii) The US importer of the product.

(iii) Retailers who sell the product in California.

However, the principal duty to comply with the requirements of the regulations that apply to responsible entities lies with the manufacturer. If the manufacturer does not comply, the importer, if any, then has a duty to comply. A retailer is required to comply with the regulations only if the manufacturer and importer(s) (if any) fail to comply, and only after this information is posted on the Failure to Comply List on DTSC's website. [Section 69501.2(a)(1)]

(2) The regulations [Section 69501.2(a)] require a responsible entity for a product to ensure compliance with the requirements pertaining to:

(i) Notifying DTSC that its product is a Priority Product [Section 69503.7], or alternatively submitting an Alternatives Analysis Threshold Exemption Notification [Sections 69503.5 and 69503.6] or a Chemical of Concern Removal Notification [Section 69505.1(g)];

(ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and

(iii) Complying with regulatory responses applicable to its product.

(3) A manufacturer or importer may opt out of complying with the above requirements by demonstrating to DTSC that the product is no longer being sold, offered for sale, distributed, supplied, or manufactured in California. [Section 69501.2 (b)]

A retailer who becomes responsible for complying with the above requirements, due to non-compliance by the manufacturer/importer, may opt out by ceasing to order the product and providing a notification to DTSC. [Section 69501.2 (c)]

If the manufacturer or importer subsequently introduces into the California marketplace a product that replaces (in terms of use and customer bases) the removed Priority Product, and that replacement product contains a Chemical of Concern, the manufacturer or importer must provide a notice to DTSC. [Section 69501.2 (b)]

(4) The regulatory requirements applicable to responsible entities may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, one or more responsible entity(ies). (This does not apply to the Priority Product Notification or Alternatives Analysis Threshold Exemption Notification requirements.) [Section 69501.2(a)(2)]

#### **D. Consequences of Non-Compliance**

(1) When DTSC determines a requirement has not been fulfilled for a product, DTSC will issue a notice of non-compliance to the manufacturer and importer(s). [Section 69501.2(d)]

(2) If the non-compliance is not remedied, the product and information concerning the product will be placed on a Failure to Comply List maintained on DTSC's website. The regulations specify the conditions under which a product will be removed from the Failure to Comply List. [Section 69501.2(d)]

(3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives analyses, regulatory responses, and various notifications and information submittals. [Article 9, Section 69509]

(4) In accordance with article 8 of chapter 6.5 of division 20 of the Health and Safety Code, DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

#### **E. Chemical and Product Information** [Section 69501.4]

DTSC's implementation of the regulations will be informed by a wealth of information that DTSC will obtain from the public domain. In addition, DTSC will request information from responsible entities for products and chemical manufacturers/importers. DTSC will maintain on its website a Response Status List that provides information as to how a responsible entity or a chemical manufacturer/importer has or has not responded to a request for information from DTSC. DTSC will also maintain on its website a Safer Consumer Products Partner Recognition List that identifies persons that have voluntarily provided DTSC with information that advances the quest for safer consumer products.

#### **F. Information on DTSC's Website** [Section 69501.5]

The regulations require DTSC to post on its website a comprehensive list of information pertaining to implementation of the regulations. In some cases, a notice of the availability of the information will be provided to persons on DTSC's electronic mailing list for these regulations. This will be DTSC's main avenue of communication with responsible entities and the public.

#### **G. Disputes** [Article 7, commencing with Section 69507]

The regulations provide a process for a responsible entity to dispute an action taken by DTSC. A requirement imposed on the responsible entity by DTSC, and posting of information in the Failure to Comply list concerning the non-compliance with that requirement, will be stayed while a dispute is pending. (The dispute process does not apply to: actions taken by DTSC with regard to the listing of Chemicals of Concern, petitions concerning the chemicals and products lists, and trade secret protection claims.)

#### **H. Certified Assessors** [Article 8, commencing with Section 69508]

Beginning two years after the regulations become effective, an AA must be conducted by or under the responsible charge of one or more persons certified as an assessor by a DTSC-designated accreditation body, as

well as meeting specified education and experience requirements. The regulations spell out the requirements for certified assessors and accreditation bodies.

## **I. Trade Secret Protection** [Article 10, commencing with Section 69510]

The regulations set out provisions for: submitting trade secret claims and the treatment of information submitted under the regulations for which a claim of trade secret protection is asserted by the submitter. The regulations are based on the authorities for handling trade secrets found in Health and Safety Code section 25257, the Uniform Trade Secrets Act (See Civil Code Section 3426.1), and the Public Records Act (See Government Code Section 6254.7).

## **II. Chemical and Product Prioritization**

### **A. Chemicals of Concern (COC) Identification**

(1) Initial List of COCs - As of the effective date of the regulations, ~1,200 chemicals are identified as COCs because they exhibit a hazard trait or an environmental or toxicological endpoint (listed in OEHHA's regulations), and are listed or identified by one or more authoritative bodies specified in the regulations. [Section 69502.2(a)] NOTE: ~500 additional chemicals currently used only in pesticides and drugs (and, thus, excluded from these regulations under Health and Safety Code section 25251) could be added to the list in the future if they are used in products that are not excluded under Health and Safety Code section 25251.

(2) Additions to the Initial List of COCs - DTSC may identify additional chemicals (that exhibit a hazard trait or an environmental or toxicological endpoint) as COCs based on consideration of the following factors [Section 69502.2(b)]:

- Chemical adverse public health and environmental impacts
- Adverse impacts of special consideration - Adverse impact(s) for:
  - (i) Sensitive subpopulations;
  - (ii) Environmentally sensitive habitats;
  - (iii) Endangered and threatened species;
  - (iv) Environments in California designated as impaired; and
  - (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
- Exposures to the chemical
- Availability of substantiating reliable information
- Availability of safer, functionally acceptable, alternative chemicals

Refer to the definitions in the regulations [Section 69501.1] for the list of adverse public health and environmental impacts, physicochemical properties, and environmental fate properties that will be considered during the identification of COCs and the prioritization of COCs/products.

(3) Listing Process - An informational list of those chemicals identified as COCs as of the effective date of the regulations will be posted on DTSC's website within 30 days after the regulations become effective. Any subsequent revisions to the list will be made in accordance with the listing process described in II.D. below. [Section 69502.3]

## **B. Chemicals of Concern and Product Prioritization**

(1) Product Prioritization Criteria [Section 69503.2(a)]: DTSC will evaluate products to determine the adverse impacts for, and exposures associated with the product, to the COCs in each product based on consideration of the factors listed below. Based on this evaluation, DTSC may list as Priority Products those products that are determined to be of high priority.

(a) Adverse Impacts and Exposures [Section 69503.2(a)(1)]: The adverse public health and environmental impacts posed by the COC(s) in the product due to exposures during the manufacture, useful life, and end-of-life disposal or management of the product, considering:

- Adverse Impacts from the COCs - The ability of the COC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering specified factors. This includes consideration of adverse impact(s) for:

- (i) Sensitive subpopulations;

- (ii) Environmentally sensitive habitats;

- (iii) Endangered and threatened species;

- (iv) Environments in California designated as impaired; and

- (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.

- Exposures - Public health and/or environmental exposures to the COC(s) in the product, considering:

- (i) Market presence information for the product;

- (ii) Reliable information regarding public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product, and reliable information demonstrating the occurrence of exposures to the COC(s) in the product;

- (iii) Information concerning the household presence and use of the product, and other products containing the same COC(s);

- (iv) Public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product during the product's life cycle; and

- (v) Product uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts.

(b) Availability of Information [Section 69503.2(a)(2)]: The availability of information to substantiate the adverse impacts and exposures.

(c) Other Regulatory Programs [Section 69503.2(a)(3)]: The scope of federal and/or other California State laws, and any applicable international trade agreements, under which the product or the COC(s) is/are regulated, and the extent to which these other regulatory requirements address, and provide protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.

(2) Key Prioritization Factors [Section 69503.2(b)]: DTSC will give priority to products meeting both of the following criteria:

- The COCs in the product have a significant ability to contribute to or cause adverse public health and environmental impacts.
- There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the COCs in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

### **C. Process to Evaluate Products [Section 69503.3]**

(1) Adverse Impacts and Exposures and Availability of Information - DTSC will begin the product evaluation and identification process by using available information to evaluate the product's adverse impact and exposure factors, along with the extent of available information.

(2) Other Regulatory Programs - DTSC will then assess whether, and to what extent, any of these adverse impacts and/or exposures pathways are adequately addressed by other California and federal laws, and international agreements. DTSC will adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment in light of any protections already provided under other laws.

(3) Priority Products - DTSC may list as a Priority Product one or more products determined to be of high priority after completion of the steps (1) and (2) described above.

(4) Safer Alternatives - DTSC may consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product.

(5) Key Prioritization Factors - Prior to issuing the proposed and final Priority Products lists, DTSC will evaluate the list for consistency with the key prioritization factors described in B.(2) above, and make adjustments as needed.

(6) Priority Product Work Plan - No later than January 1, 2014, DTSC will issue a Priority Product Work Plan that identifies the product categories that will be evaluated to identify products to be added in the future to the Priority Products list during the next three years. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan.

(7) Initial Priority Products List - Prior to January 1, 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more COCs in the product meeting specified criteria.

### **D. Listing Process [Sections 69502.4 and 69503.7]**

- (1) Prior to finalizing each augmentation to the initial COCs list, and the initial and revised Priority Products list, DTSC will make the proposed list available for public review and comment for a minimum 45-day period.
- (2) After consideration of public comments on a proposed list, DTSC will finalize and post the final list on its website.
- (3) DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.
- (4) The initial proposed list of Priority Products, which will include no more than five products, will be made available for public review and comment no later than 180 days after the effective date of the regulations.
- (5) For some products, DTSC will specify in the Priority Products list the product component, or the homogenous material within a component, that is the required minimum focus of the alternatives analysis for the product.
- (6) Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification, an Alternatives Analysis Threshold Exemption Notification, Priority Product Removal Notification, or a COC Removal Notification within 60 days after the product is listed as a Priority Product.

#### **E. Petition Process** *[Sections 69504 and 69504.1]*

Subject to one specified exception, any person may petition DTSC to add or remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's legislative and/or regulatory authorities. After granting a petition, DTSC will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes described above.

#### **F. Alternatives Analysis Threshold Exemption**

- (1) A product that is listed as a Priority Product and that meets the criteria for an alternatives analysis exemption will be exempt from the requirement to perform an alternatives analysis, if the responsible entity submits an Alternatives Analysis Threshold Exemption Notification. *[Section 69503.5(a)]*
- (2) An alternatives analysis exemption applies only to products in which the concentration of the COC(s), that are the basis for the product being listed as a Priority Product, does not exceed the applicable alternatives analysis threshold specified by DTSC. *[Section 69503.5(b)]*
- (3) The regulations specify criteria to be used by DTSC when setting the alternatives analysis threshold for each COC in a Priority Product. This includes: (i) the ease or difficulty of removing the COC from the product if the COC is a contaminant rather than an ingredient; (ii) the detection limit for the COC; and (iii) various public health and environmental protection considerations. In no case may DTSC specify an alternatives analysis threshold that is lower than the detection limit for the COC. *[Section 69503.5(c)]*
- (4) If multiple COCs that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such COCs. *[Section 69503.5(d)]*

(5) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification [Section 69503.6(a)]. The responsible entity is required to notify DTSC if the information in the Alternatives Analysis Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an alternatives analysis exemption [Section 69503.6 (c) and (d)].

### **III. Alternatives Analyses (AAs)**

#### **A. Guidance Materials**

The regulations require DTSC to prepare, and make available on its website, guidance materials to assist persons in performing AAs, and to post on its website AAs that are available in the public domain and are supported by reliable information. [Section 69505]

#### **B Alternatives Analyses - General Requirements**

(1) A responsible entity for a Priority Product must conduct an AA for the Priority Product, and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. [Section 69505.1(c)]

- The Preliminary AA Report must be submitted no later than 180 days after the date the product is listed on the final Priority Products list, unless DTSC specifies a different due date for the product in the Priority Products list.

- The Final AA Report must be submitted no later than 12 months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, and DTSC approves, a longer period of time not to exceed 24 months (or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered).

(2) The regulations allow for a responsible entity to request a one-time extension, not to exceed 90 days, for submitting the Preliminary and/or Final AA Report, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. [Section 69505.1(d)]

(3) Each AA completed two years or later after the effective date of the regulations must be performed, and each Preliminary and Final AA Report submitted two years or later after the effective date of the regulations must be prepared, by or under the responsible charge of an assessor certified by an accreditation body designated by DTSC. [Section 69505.1(e)] (See Article 8, commencing with Section 69508, of the regulations for further details concerning assessor requirements and accreditation bodies.)

(4) The regulations allow a responsible entity to fulfill the AA requirements by submitting a report for a previously completed AA for the Priority Product - if DTSC determines that the report is substantially equivalent to the AA Report requirements specified in the regulations, and that the report contains sufficient information to identify regulatory response(s). [Section 69505.1(f)]

(5) If a responsible entity reformulates the Priority Product to remove the COC(s), that is/are the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to the Department in lieu of conducting an AA and submitting an AA Report. [Section 69505.1(g)]

#### **C. Analysis of Priority Products and Alternatives**

(1) The regulations require that each AA be conducted in two stages. The Preliminary AA Report is submitted to DTSC after completion of the first AA stage, and the Final AA Report is submitted after completion of the second AA stage. [Section 69505.2(a)]

(2) *The first stage of the AA includes:*

(a) Step 1, Identification of Product Requirements and Function of COCs [Section 69505.3(b)(1)]:

- The function, performance, and legal requirements associated with the Priority Product that must be met by alternatives being considered.
- The function of the COC(s) in meeting the Priority Product's function, performance, and legal requirements.
- A determination as to whether the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements.
- If it is determined that neither the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product requirements, the removal of the COC(s) from the Priority Product without the addition of substitute chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.

(b) Step 2, Identification of Alternatives [Section 69505.3(b)(2)]:

Identification of alternatives for consideration that meet the requirements for the Priority Product, and eliminate or reduce the concentration of the COC(s) in the Priority Product and/or reduce or restrict for public health and/or environmental exposures to the COC(s) in the Priority Product. The responsible entity is required to include in the AA consideration of any identified existing viable alternatives.

(c) Step 3, Initial Screening of Alternative Chemicals [Section 69505.3(b)(3)]:

- The responsible entity is required to collect and use available relevant information to identify the adverse public health and environmental impacts associated with each chemical being considered as an alternative to the COC(s) in the Priority Product.
- Using this information, the responsible entity must compare each of the identified alternative chemicals with the COC(s) in the Priority Product.
- The responsible entity must eliminate from further consideration in the AA any alternative chemical that it determines poses equal or greater adverse public health and/or environmental impacts than the COC(s).

(d) Step 4, Consideration of Additional Information [Section 69505.3(b)(4)]:

As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above.

(e) Step 5, Identification of Next Steps [Section 69505.3(b)(5)]:

The responsible entity is required to prepare a work plan and proposed implementation schedule for completion of the second AA stage, as described in (3) below, and preparation and submittal of the Final AA Report.

Abridged AA Report [Section 69505.2(b)]:

A responsible entity, that determines (after completion of steps 1 through 4 above) that a functionally acceptable alternative is not available or feasible, may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements.

(3) *The second stage of the AA includes:*

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives [*Section 69505.4(a)*]:

• A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:

(i) It makes a demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration, and

(ii) There is a demonstrable difference in the factor's contribution to such impacts between two or more of the alternatives being considered.

• The responsible entity must use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives under consideration:

(i) Multimedia life cycle impacts and Chemical hazards:

- Adverse environmental impacts
- Adverse public health impacts
- Adverse waste and end-of-life impacts
- Environmental fate properties
- Materials and resource consumption impacts
- Physical chemical hazards
- Physicochemical properties

(ii) Product function and performance

(iii) Economic impacts

• The identification of relevant exposure pathways must consider:

(i) Chemical quantity information

(ii) Exposure factors

(b) Step 2, Comparison of the Priority Product and Alternatives [*Section 69505.4(b)*]:

The responsible entity must use available quantitative information and analyses, supplemented by available qualitative information and analyses, to evaluate and compare the Priority Product and each alternative with respect to each relevant factor and associated exposure pathways and life cycle segments.

(c) Step 3, Alternative Selection Decision [*Section 69505.4(c)*]:

The responsible entity selects the alternative that will replace or modify the Priority Product, or decides to retain the Priority Product.

(d) Step 4, Consideration of Additional Information [*Section 69505.4(d)*]:

As part of the second stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including reconsideration of factors evaluated in the first stage of the AA.

(e) Step 5, Identification of Next Steps [*Section 69505.4(e)*]:

The responsible entity is required to prepare a Final AA Report that includes an implementation schedule for implementing the selected alternative, if any, and/or any proposed regulatory responses.

(4) A responsible entity may use an AA process that differs from the process described above if certain requirements are met, including [*Section 69505.2(c)*]:

- The alternate process will provide the information needed to prepare an AA Report that substantially meets the AA Report requirements specified in the regulations.
- The alternate process will compare the Priority Product and the alternatives using the same factors and associated exposure pathways and life cycle segments that would be used if the process specified in the regulations was followed.
- The responsible entity submits a work plan to DTSC for the alternate process no later than 60 days after the product is included on the Priority Products list.

#### **D. Alternatives Analysis Reports**

(1) The Preliminary and Final AA Reports must include the information listed below. All differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report must be identified and explained in the Final AA Report. [*Section 69505.5(a)*]

- An **executive summary** [*Section 69505.5(b)*]. The executive summary cannot include any information for which trade secret protection is claimed - this will enable the executive summary to be posted on DTSC's website in its entirety.
- Information regarding the **preparer** of the AA Report [*Section 69505.5(c)*]
- Information regarding the **responsible entity** and the **supply chain** for the product [*Section 69505.5(d)*]
- Information describing the **Priority Product** and the **COCs** [*Section 69505.5(e)*]
- A description of the **alternatives** chosen to be evaluated and compared, and an explanation of the rationales for selecting and screening out specific alternatives at each stage of the alternatives comparison process. [*Section 69505.5(f)*]

- Detailed information on the **evaluation and comparison of the Priority Product and its alternatives** for all of the relevant comparison factors, and associated exposure pathways and life cycle segments. *[Section 69505.5(f)]*

- Identification of **comparison factors**. The AA Reports must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must explain the rationales for each factor, exposure pathway, and life cycle segment determined not be relevant. *[Section 69505.5(g)]*

- A description of the **methodology** used to conduct the AA *[Section 69505.5(h)]*

- Identification of all information used as **supporting information** in performance of the AA and preparation of the AA Reports. This information must be made available to DTSC, upon request. The Final AA Report must also identify any **information gaps**. *[Section 69505.5(i)]*

- Identification and description of the **alternative selected** to replace or modify the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative, if any; and any **proposed regulatory responses**. *[Section 69505.5 (j) and (k)]*

(2) The information in the Final AA Report concerning the alternative selection decision must include:

- A description of the alternative, if any, selected, and the rationales for the selection decision. This includes an analysis that evaluates and compares the selected alternative against the Priority Product, and an explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. *[Section 69505.5(j)(2)]*

- A discussion of the functional and performance acceptability of the selected alternative as compared to the Priority Product. If no alternative is selected, this information must be provided for each alternative considered. *[Section 69505.5(j)(2)(A)]*

- The rationales for selecting an alternative that retains one or more COC(s) or uses substitute chemicals, if it is determined during the AA that neither the COC(s) nor substitute chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements). *[Section 69505.5(j)(2)(B)]*

- A list of all chemicals known, based on available information, to be in the selected alternative that differ in type, or are present at a higher concentration, relative to the chemicals contained in the Priority Product; available environmental fate information for the chemicals; available hazard trait and environmental and toxicological endpoint information for those chemicals; and available chemical identification and description information for those chemicals. *[Section 69505.5(j)(2)(C)]*

(3) After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes prior to introduction of the new product into the California marketplace, the responsible entity is required to submit a revised Final AA Report with an explanation of the change. A revised Final AA Report is also required if the original alternative selection decision was to retain the Priority Product, and the responsible entity later decides to replace the Priority Product with an alternative product. *[Section 69505.2(d)]*

#### **E. DTSC Review and Determinations for AA Reports** *[Section 69505.6]*

(1) Within 60 days of receiving an AA Report, DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. Notices of

deficiency will generally give the responsible entity 60 days to remedy the deficiency. If the submitter of the AA Report fails to adequately and timely respond to 2 notices of deficiency for the Final AA Report (or 1 notice of deficiency for the Preliminary AA Report), the product will be placed on the Failure to Comply List.

(2) Notices of compliance for Preliminary AA Reports will specify the due date for submitting the Final AA Report, which will range from 12 to 24 months (or up to 36 months if regulatory safety and/or performance testing is required for alternatives being considered) after DTSC issues the notice of compliance. In the notice of compliance for the Final AA Report, or in a separate notice, DTSC will provide notice of its proposed determination as to whether one or more of the regulatory responses that are triggered by a DTSC determination or other action (as described below) are required. The regulatory response determination does not become final until completion of the regulatory response public notice and comment process described below.

#### **IV. Regulatory Responses**

##### **A. Regulatory Response Selection Principles [Section 69506]**

(1) DTSC will require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.

(2) DTSC will give preference to regulatory responses providing the greatest level of inherent protection (i.e., avoidance or reduction of adverse impact or exposure achieved through product or process redesign, rather than through administrative or engineering controls designed to limit exposure to a COC in a product.

(3) In selecting regulatory responses, DTSC may consider any or all of the following factors:

- The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product;
- The relative cost-effectiveness of the regulatory response as compared to other possible responses;
- The administrative and other burdens that would be placed upon DTSC, the responsible entities, the product end-users, and the public;
- Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations; and
- The ease and efficacy of enforcement of the regulatory response.

##### **B. Applicability**

(1) The regulations specify regulatory responses that will, under specified conditions, apply to [Section 69506.1(a)]:

- Products manufactured as a selected alternative following completion of an AA;
- Priority Products for which an alternative is not selected; and
- Priority Products that will remain in commerce pending development and distribution of the selected alternative.

(2) No regulatory response (other than providing supplemental AA Report information if requested by DTSC) will be required for a selected alternative, if DTSC determines that no regulatory response is necessary to protect, prevent or limit adverse public health or environmental impacts [Section 69506.3]

### **C. Regulatory Response Process** [Sections 69506.1 (b)-(d) and 69506.12]

(1) For regulatory responses triggered by a DTSC determination or other action (including use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects), DTSC will notify affected responsible entities of its proposed regulatory response determination.

(2) The proposed regulatory response determination will also be made available for public review and comment for a minimum 45-day period.

(3) After consideration of public comments, DTSC will send a final determination notice to the responsible entity(ies) and post the final notice on its website.

(4) The responsible entity must notify DTSC, and California retailers of affected consumer products, of the applicability of regulatory responses to the responsible entity's product within 30 days.

(5) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response, and (if applicable) upon completion of the implementation of the selected alternative.

(6) DTSC will post on its website a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product (and each Priority Product, as applicable), and the implementation dates for the alternative product, if any, and the regulatory response(s).

### **D. Supplemental AA Report Information** [Section 69506.2]

(1) If required by DTSC, a responsible entity must provide any information DTSC determines is necessary to select and ensure implementation of regulatory responses.

(2) If required by DTSC, a responsible entity must obtain/develop and provide to DTSC information to fill one or more information gaps identified during the AA, if DTSC determines this information is needed to re-evaluate the initial regulatory response(s) imposed for the product.

### **E. Self-Implementing Regulatory Responses**

The regulations set forth specific circumstances under which the following regulatory responses will always be required, along with implementation due dates:

(1) Product Information for Consumers. Product information must be provided to consumers (within 12 months) if the alternative product contains a COC in exceedance of the applicable alternatives analysis threshold, or if the manufacturer chooses to retain the Priority Product (indefinitely or for more than 12 months pending development and distribution of the alternative product). The regulations specify the types of information that must be provided to consumers, and the mechanisms that must be used to provide the information. [Section 69506.4]

(2) End-of-Life Product Management Program. A responsible entity must establish, maintain, and fund (within 1 year) an end-of-life product stewardship program, and provide product information to consumers, if the alternative product (or the Priority Product, if the manufacturer chooses to retain the Priority Product) is

required to be managed as a hazardous waste in California at end-of-life. The requirements for the product stewardship plan and program are specified in the regulations. [Section 69506.8]

## **F. Regulatory Responses Triggered by a DTSC Determination or Other Action**

(1) Use Restrictions. DTSC may impose specified restrictions on the use of COCs in a product, or restrictions on the use of the product itself, to reduce the amount of a COC in the product, or reduce the ability of the product to contribute to or cause an exposure to the COC in the product. [Section 69506.5]

(2) Product Sales Prohibition. If the selected alternative contains a COC above the applicable alternatives analysis threshold (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following within 1 year (or sooner if required by DTSC) [Section 69506.6]:

- Ensure that the Priority Product is no longer sold in California; or
- Submit to DTSC an AA Report that selects an alternative that does not contain a COC.

DTSC may also impose a product sales prohibition in the absence of a determination that there is a safer, functionally acceptable, and technologically and economically feasible alternative, unless the responsible entity demonstrates to DTSC's satisfaction that: (i) the overall beneficial public health and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and (ii) administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.

(3) Engineering or Administrative Controls. Under specified conditions, DTSC may impose requirements that control access to or limit exposure to COCs in a product to reduce the likelihood of adverse public health and/or environmental impacts. This may include controls that integrally contain a COC within the structure of a product. [Section 69506.7]

(4) Advancement of Green Chemistry and Green Engineering. DTSC may require a manufacturer to initiate a research and development project or fund a challenge grant that uses green chemistry and/or green engineering principles to: (i) design a safer alternative; (ii) improve the performance of a safer alternative; (iii) decrease the cost of a safer alternative; and/or (iv) increase the market penetration of a safer alternative. [Section 69506.9]

(5) Other Regulatory Responses. DTSC may impose one or more regulatory responses described above to situations that may differ from the specific situations described above. DTSC may periodically re-evaluate any regulatory response imposed under this provision. DTSC may also require a new AA to be performed, and new Preliminary and Final AA Reports to be submitted. [Section 69506.10]

## **G. Regulatory Response Exemptions [Section 69506.11]**

The regulations provide a process for a responsible entity to request an exemption from an otherwise applicable regulatory response (other than the requirement to provide to DTSC information supplemental to an AA Report) based on either or both of the following:

(1) The required regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement, in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict.

(2) The required regulatory response substantially duplicates a requirement of another California or federal regulatory program or an international trade agreement without conferring additional public health or environmental protection benefits.

## **Existing Laws and Regulations**

### State Law

Existing law establishes the Department of Toxic Substances Control, in the California Environmental Protection Agency, with powers and duties regarding, among other things, hazardous waste disposal, underground storage of hazardous substances and waste, and the handling and release of hazardous materials.

Health and Safety Code section 25252 requires DTSC to adopt regulations to establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized for consideration as being chemicals of concern. This process is required to include, at a minimum, consideration of: (i) the volume of a chemical in commerce in California, (ii) the potential for exposure to a chemical in a consumer product, and (iii) potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. These criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) is required to specify. The requirement imposed on OEHHA is set out in Health and Safety Code section 25256.1. The endpoints developed by OEHHA will also be included in the Toxics Information Clearinghouse that DTSC is required to establish pursuant to Health and Safety Code section 25256.

Health and Safety Code section 25252 also directs DTSC, in adopting these regulations, to reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies. However, the statute provides that DTSC is not limited to referencing and using only this information.

Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that, at a minimum, take into consideration: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts.

Health and Safety Code section 25253 also requires that the regulations specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, requiring: no regulatory response; additional information to be provided to DTSC needed to assess a chemical of concern and its potential alternatives; labeling or other types of product information; a restriction on, or prohibition of, the use of a chemical of concern in a consumer product; controlling access to or limiting exposure to the chemical of concern in a consumer product; managing the product at the end of its useful life; funding green chemistry challenge grants; and any other outcome DTSC determines accomplishes the requirements of the authorizing statute.

Health and Safety Code section 25251 defines "consumer product", for purposes of the regulations required by Health and Safety Code sections 25252 and 25253, to mean a product or part of a product that is used, bought,

or leased for use by a person for any purpose. However, "consumer product" does not include: dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials and medical devices; food; or pesticides. (Mercury-containing lights were exempted through December 31, 2011.)

Health and Safety Code section 25257 establishes a procedure for the protection of information submitted to DTSC, for purposes of Health and Safety Code sections 25252 and 25253, that is claimed to be a trade secret.

Health and Safety Code section 25257.1 states that DTSC is not authorized to supersede the regulatory authority of any other department or agency, and that DTSC shall not adopt duplicative or conflicting regulations for product categories already regulated, or subject to pending regulation, consistent with the purposes of Health and Safety Code sections 25252 and 25253.

Article 8 of chapter 6.5 of division 20 of the Health and Safety Code sets forth DTSC's authority and mechanisms for enforcing the provisions of chapter 6.5 (which includes the above-listed statutes) and the regulations adopted pursuant thereto.

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991) grants DTSC authority to adopt and enforce regulations for execution of its duties.

### Federal Law

The federal Toxic Substances Control Act of 1976 (TSCA) (Title 15, United States Code, commencing with Section 2601) authorizes the United States Environmental Protection Agency (USEPA) to require reporting, record-keeping and testing requirements, and to set restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides. TSCA addresses the production, importation, use, and disposal of specific chemicals. Among its provisions, TSCA requires USEPA to maintain the TSCA inventory, which currently contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the TSCA inventory.

TSCA requires the submission of health and safety studies that are known or available to those who manufacture, process, or distribute in commerce specified chemicals, and allows USEPA to gather information from manufacturers and processors about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed. However, there were 62,000 chemicals in use in 1976 when TSCA was adopted into federal law. TSCA provides a "grandfather" clause for those 62,000 chemicals. Therefore, these 62,000 chemicals are not subject to the information-gathering requirements in TSCA.

TSCA places the responsibility for conducting health and environmental impact testing on USEPA, not the producer of the chemical substance or mixture. To date, USEPA has conducted testing and published data on only 200 chemicals in the inventory of 83,000 chemicals.

In 2009, the United States Government Accountability Office, an investigative arm of the United States Congress, found USEPA's implementation of TSCA to be "high-risk" because "EPA has failed to develop sufficient chemical assessment information on the toxicity of many chemicals that may be found in the environment as well as tens of thousands of chemicals used commercially in the United States".

### **Relation to Existing Federal Law**

The proposed regulations by DTSC do not duplicate or conflict with existing federal law. The initiative for safer consumer products was developed, to a great extent, to address structural weaknesses in the federal Toxic Substances Control Act of 1976 ("TSCA", Title 15, United States Code, section 2601 et seq.). TSCA places the cost of obtaining data about chemical safety on the United States Environmental Protection Agency (US EPA) rather than requiring the chemical companies to develop and submit such information. Consequently, information about the 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on the health or environmental effects of many of these chemicals.

### **Relation to Existing Federal and State Regulations**

Some of the chemicals and products that potentially may become subject to these regulations are also regulated to some degree by other existing federal or State regulatory programs. However, consistent with Health and Safety Code section 25257.1(c), these regulations contain provisions (for example, sections 69503.2(a)(3) and 69506.11) that expressly work to ensure that there is no duplication or conflict with other federal or State regulations. More specifically, the regulations require DTSC to take into consideration the nature and extent of existing or pending State or federal regulations of the same entities for the same chemicals and/or products so as to avoid duplicative or conflicting regulation under this program.

In addition, DTSC has worked closely with several sister agencies whose regulatory purview is closest to that of DTSC under these regulations. In particular, DTSC worked with OEHHA, the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies. Finally, DTSC has conducted extensive public outreach, including public workshops, public hearings, and public comment periods. DTSC has not received any comments during any of these opportunities for comment indicating that its regulations conflict with other State or federal regulations.

### **CONSIDERATION OF ALTERNATIVES**

DTSC must determine that no reasonable alternative is considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which these regulations are proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this notice.

DTSC considered and rejected the following alternatives.

1. Do Nothing. DTSC rejected this option because Health and Safety Code sections 25252 and 25253 *require* DTSC to adopt regulations that address chemicals of concern in consumer products. So, this is not a lawful option.
2. Products and Chemical Hazard Categories Prioritization Process to Develop Safer Consumer Products. Again, after much consideration and input, DTSC determined that this approach may not fully comport with the authorizing statute. DTSC also became concerned that there was a lack of DTSC oversight during various stages of the proposed process. Many stakeholders were also very skeptical of this approach. For all these reasons, this alternative was rejected.
3. Other Options Considered in Earlier Proposed Drafts of the Regulations. DTSC released two other drafts of these regulations in 2010. During the public comment periods for the two prior formal regulatory proposals, DTSC received thousands of specific comments from hundreds of commenters suggesting other approaches to various provisions in the regulations. DTSC has again considered those comments, as well as input during

meetings of the Green Ribbon Science Panel and in other informal meetings. All of this input has led DTSC to revise various provisions that were in prior versions of both formally and informally proposed iterations of the regulations.

## MANDATES ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DTSC has made a determination that adoption of this regulation will not impose a local mandate or result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code or other nondiscretionary costs or savings to local agencies.

## COST OR SAVINGS TO STATE OR LOCAL AGENCIES, OR SCHOOL DISTRICTS SUBJECT TO REIMBURSEMENT

DTSC has made a determination that adoption of these regulations will not: (i) impose a local mandate, (ii) result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code, (iii) impose any other non-discretionary costs or savings on local agencies, or (iv) result in any decrease in federal funds to California as a result of these regulations.

These regulations address chemicals in products and any fiscal impact from the regulation on local agencies would likely be in the operating expense and possibly equipment line items. However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of competitive safer products readily available at competitive prices. (Please see a more detailed explanation immediately below in the Fiscal Impact section.)

Any costs incurred by local government agencies would not likely be state-reimbursable because any increase in costs would not be unique to local government and would apply generally to all entities purchasing the same products.

## COST OR SAVINGS TO ANY STATE AGENCY

### **Cost of Goods**

These regulations address chemicals in products and any fiscal impact from the regulation on State agencies would likely be in the operating expense and possibly equipment line items.

However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of comparable safer products readily available at competitive prices. This will provide the incentive for companies that redesign their products to keep prices for the redesigned products competitive. It will also ensure that agencies, and other consumers, have a wide variety of products to choose from at competitive prices (even if the particular brand they are using is replaced with a higher price product).

It is important to note that nothing in the regulations would force an agency to buy a particular product or to replace in-use items (e.g., carpet, furniture, paint). However, these regulations will have the benefit of making more information available for state and local agencies to assist them in making their own discretionary purchasing decisions for their environmentally preferable purchasing programs.

Even if DTSC ends up banning a product, cost impacts are not expected because of the wide variety of comparable safer products readily available at competitive prices.

## **DTSC State Operations Expenditures**

The implementation activities during the first three years will include: preparing Chemicals of Concern and Priority Product lists; developing guidance for businesses and other interested parties; determining data needs; and performing legal review of: trade secret claims, chemical and product lists, various notifications and guidance and information requests.

In future years, as the program is fully implemented through all phases (chemical and product prioritization, alternatives analyses, and regulatory responses), operational and programmatic needs will increase, and DTSC will need additional resources. In these out years, businesses will begin submitting alternatives analyses and the scope of chemicals listed as Chemicals of Concern and products listed as Priority Products will expand. Thus, DTSC's resource needs will grow over time based on the need to research and evaluate additional chemicals and products, review alternatives analysis work plan and reports (including review of trade secret protection claims), develop and monitor regulatory responses, and enforce compliance with the alternatives analysis and regulatory response requirements.

## DETERMINATION OF ADVERSE STATEWIDE ECONOMIC IMPACT

DTSC has made a determination that this regulation may have a significant statewide economic impact directly affecting businesses, but that it is not expected to affect the ability of California businesses to compete with businesses in other states. It is important to note that the regulations apply with equal force to businesses in California and those outside of California. This is because the regulations apply to those businesses placing consumer products into the stream of commerce in California - regardless of the place of manufacture of those products. DTSC is unable to quantify the economic impact on businesses but has outlined factors that will increase or decrease the economic impact to businesses. Until DTSC prepares the Priority Products list, there is no way to know which or how many products will be on the list or how many businesses will be required to perform an alternatives analysis. Likewise, it is not possible to estimate how many businesses will be subject to regulatory responses.

### **Types of Businesses Affected**

Businesses impacted will primarily be those that directly or indirectly make a Priority Product available in California's stream of commerce. Businesses involved in the supply chain of Chemicals of Concern contained in Priority Products will also be impacted. To a lesser degree, businesses in the supply chain for a broader range of products (and chemicals contained those products) placed into California's stream of commerce will be impacted, but only with respect to voluntarily providing chemical and product information to DTSC upon request. The regulation impacts both out-of-state and in-state businesses. This includes: chemical and product producers, brand name manufacturers, importers and retailers in the supply chain for a Priority Product.

### **Projected Compliance Requirements**

Compliance requirements will vary from business to business depending on the products they produce, sell or import, and the arrangements that are made between the various responsible entities in the supply chain for each product. Some businesses will have no compliance requirements. Others will be required to comply with one or more of the following types of requirements: performance of alternatives analyses and submission of alternatives analyses work plans and reports for Priority Products (or submission of various notifications to DTSC in lieu of complying with alternatives analysis requirements); and compliance with regulatory responses imposed on selected products by DTSC after completion of an alternatives analysis. California retailers, in particular, for a product subject to these compliance requirements can "opt out" by ceasing to sell a Priority Product. Manufacturers and importers also have various options for less rigorous compliance than the general compliance rules depending on what actions they take regarding a Chemical of Concern present in a Priority Product.

In developing these regulations, DTSC has sought to minimize the impact on businesses by:

- Making responses to DTSC requests for information on chemicals and products optional instead of mandatory.
- Providing options to extend compliance deadlines.
- Allowing businesses to meet the requirements of the regulations through consortiums, partnerships and similar arrangements.
- Providing guidance documents and sample alternatives analyses.
- Providing exemptions for products containing only threshold amounts of chemicals of concern.
- Providing flexibility in the alternatives analysis process.
- Allowing businesses to submit alternatives analyses that do not have all the required data. Businesses would only be required to fill data gaps if DTSC requires the additional data as a component of a regulatory response.
- Allowing businesses to avoid the alternatives analysis requirement by notifying DTSC that the chemical of concern has been removed from the product.

These regulations do not require all businesses to prepare reports. The regulations also do not impose any annual or other on-going reporting requirements on any businesses.

The regulations do allow DTSC to request businesses to provide information to DTSC (using existing information or by developing new information). There is no mandate for businesses to provide such information requested by DTSC (except as part of the Alternatives Analysis process or as a regulatory response requirement). Also, responsible entities that have a Priority Product would have to conduct an Alternatives Analysis and submit work plans and preliminary and final Alternative Analysis Reports. For the reasons described under A.2 and B.1 /B.2 of this attachment, DTSC cannot estimate the costs to businesses of providing requested information or completing the Alternatives Analysis Reports until implementation is under way.

DTSC finds that it is necessary for the health, safety, or welfare of the people of California that the reporting requirements that are compulsory apply to businesses subject to these regulations.

#### COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

These regulations do not impose new responsibilities for private persons. These regulations do impact products made available for sale in California and may have the effect of increasing the costs of products identified as Priority Products or their alternatives. The impacts on consumers will be proportionate to the amount of their budget spent on Priority Products. If the Priority Products represent a small proportion of consumer expenditures, then the impacts to individual consumers should not be significant. It is anticipated that competition will protect consumers from facing higher prices for consumer products. Additionally, it is anticipated that at least some consumers will realize cost savings from the use of safer products that do not present the health threats associated with Priority Products.

As discussed above, DTSC has made a determination that this regulation will have an economic impact on businesses. However, DTSC is unable to quantify the economic impact on businesses. In particular, DTSC is unable to quantify the cost impacts on a "representative" business, as the compliance requirements will vary from business to business depending on: (i) which products are listed as Priority Products, (ii) which products

each business produces, sells, distributes or imports, and (iii) the arrangements that are made between the various responsible entities in the supply chain for each Priority Product.

## RESULTS OF REGULATORY ECONOMIC IMPACT ANALYSIS

DTSC has made the determination that the regulation may have a possible short-term minimal impact on the reduction of jobs, with a much larger potential for creation of new jobs as new materials and processes are developed. DTSC cannot estimate the number of jobs created or eliminated by the regulations.

DTSC has made the determination that the regulation may result in the creation of new businesses as new materials and processes are created, with the potential for expanded export markets for California-made products. Furthermore, current firms have time to adapt prioritized consumer products to meet regulatory requirements. Since DTSC does not know which products will become subject to the requirement to perform an alternatives analysis, it cannot predict the number of businesses that may be created or eliminated.

DTSC has made the determination that the regulation provides opportunities for growth as California businesses have access to a wider range of safer consumer products and can provide services and products for an expanding number of consumers demanding safer and greener products. It is thought that California businesses working to study, develop and promote safer and greener consumer products will benefit from these regulations.

The rulemaking may have a significant statewide economic impact directly affecting some businesses. However, the benefits of this rulemaking outweigh any adverse economic impacts. Not only does the rulemaking aim to protect public health and the environment from harmful toxic substances, it also presents the potential for the creation of new businesses and jobs and for the market expansion of safer and greener products.

## EFFECT ON HOUSING COSTS

DTSC has made a determination that there will be no impact on housing costs.

## EFFECT ON SMALL BUSINESSES (1 CCR 4)

DTSC has determined that these regulations will have an effect on small businesses. However, DTSC is unable to quantify the economic impact on small businesses for the reasons discussed above. DTSC has considered alternatives for small businesses to ameliorate the impacts of compliance with the regulations for such businesses (e.g., allowing small businesses longer time frames than other businesses to meet the requirements of the regulations). However, based upon prior public comments received on the proposed regulations, and a re-evaluation of alternatives considered, DTSC has determined that the statutes authorizing and mandating these regulations do not provide the authority to apply these regulations in a differential manner based upon the size of a business. Nonetheless, DTSC has determined that the Alternatives Analysis Guidance, that is required to be prepared by DTSC, will disproportionately work to the benefit of small businesses. This is because larger businesses may already possess, or have ready access to, expertise to assist them in complying with the regulations.

## CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) COMPLIANCE

DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.). This rulemaking meets the statutory exemption available under subdivision (b)(8) of Public Resources Code section 21080. A draft Notice of Exemption is available for review with the rulemaking file and will be filed with the State Clearinghouse when the regulations are adopted.

## PEER REVIEW

DTSC is having the scientific basis of these regulations peer reviewed pursuant to Health and Safety Code section 57004.

## CALIFORNIA ENVIRONMENTAL POLICY COUNCIL REVIEW

As required by Health and Safety Code section 25252.5, DTSC will be submitting the proposed regulations to the California Environmental Policy Council (CEPC) for review after the close of the public comment period and a determination as to whether the proposed regulations require revisions.

## CONTACT PERSONS

Inquiries regarding technical aspects of the proposed regulations or CEQA documents may be directed to Odette Madriago of DTSC at (916) 323-4927 or, if unavailable, Corey Yep of DTSC at 916-445-3601. However, such oral inquiries are not part of the rulemaking record.

A public comment period has been established commencing on July 27, 2012, and closing on **September 11, 2012** for statements, arguments, or contentions regarding the rulemaking and/or supporting documents that must be submitted in writing or may be presented orally or in writing at the public hearing in order for them to be considered by DTSC before it adopts, amends, or repeals these regulations.

## AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

Copies of the Notice, Initial Statement of Reasons, the text of the proposed regulations, all the information upon which its proposal is based, and the express terms of the proposed regulations are posted to DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> or may be obtained from **Kryisia Von Burg** of DTSC's Regulations Section as specified below.

After the close of the comment period, DTSC may adopt the proposed regulations. If substantial changes are made, the modified full text will be made available for comment for at least 15 days prior to adoption. Only persons who request the specific proposed regulations, attend the hearing, or provide written comments on this specific regulation will be sent a copy of the modified text if substantive changes are made.

Once the regulations have been adopted, DTSC prepares a Final Statement of Reasons which updates the Initial Statement of Reasons, summarizes how DTSC addressed comments and includes other materials, as required by Government Code section 11346.9. Copies of the Final Statement of Reasons may be obtained from **Kryisia Von Burg** at the address listed below. A copy of the Final Statement of Reasons will also be posted on DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>, along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulations.

To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <http://www.dtsc.ca.gov/ContactDTSC/ELists.cfm> and subscribe to the applicable electronic mailing list or e-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

Please direct all written comments, procedural inquiries, and requests for documents by mail, e-mail, or fax to:

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control

P.O. Box 806  
Sacramento, CA 95812-0806

E-mail Address: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Fax Number: (916) 324-1808

Ms. Von Burg's phone number is (916) 324-2810. If Ms. Von Burg is unavailable, please call Mr. Cordova at (916) 324-7193.

---

\*The regulations provide a process for any individual or organization (including federal and other California State agencies) to petition DTSC to add/remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. *[Article 4]*

-----  
This e-mail may contain confidential material. If you are not an intended recipient, please notify the sender and delete all copies. It may also contain personal views which are not the views of CQ Roll Call or its owner, The Economist Group. We may monitor e-mail to and from our network. For company information go to <http://legal.economistgroup.com>.

October 11, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812

COMMENT ON SAFER CONSUMER PRODUCTS REGULATIONS  
DSTC REFERENCE NO.R-2011-02, OAL FILE NUMBER Z-2012-0717-04

MWS Wire Industries is a wire manufacturing and distribution business operating in California since 1968. The company employs 45 people as a supplier of high quality, high reliability products to manufacturers in the medical device, aerospace, automotive and other critical industries.

The company uses solvents with hazardous properties that sooner or later may be Chemicals of Concern subject to the proposed Safer Consumer Products regulations. In this regard MWS Wire emphasizes that use of hazardous materials in the workplace is already subject to substantial state and federal worker protection regulations: providing detailed hazard information, initial and periodic training of workers in safe handling procedures, definitive OSHA PEL's, protective equipment, engineered safety measures and controls and so on. In view of these worker protections, MWS Wire strongly objects to the portion of section 69503.2 Priority Products Prioritization Factors that lumps in workers with "customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other locations;" None of these groups have the benefit of training and other safeguards already noted that prepare and protect workers using hazardous materials. To include workers in this way is misguided and violates the express requirement that these regulations not duplicate existing ones.

For the same reasons the company objects to Section 69501.1 Definitions, (58) "Sensitive subpopulations," which includes "workers with greater exposures due to the nature of their occupation." Leaving aside the fact that including workers who are exposed to hazardous chemicals duplicates existing worker protection regulations, what does "greater exposure" mean? Certainly a worker who has been given information, training, protective equipment and a properly engineered work environment has far less exposure and is at far less risk than infants, children, pregnant women and the elderly who lack basic protections. It is absurd to classify workers with significant knowledge, training and other protections with people that have none of these advantages.

Since the first electrical wire coatings were formulated a century ago, the industry has invested in research for alternatives to expensive solvents but thermal and electrical performance has proved inferior when less toxic chemicals and production methods have been tried. The solvents in use today are essential for producing high reliability products that meet stringent safety and performance standards mandated by our customers and third parties such as Underwriters Laboratories.

MWS Wire Industries urges DTSC to tightly focus the Safer Consumer Products regulations where it will have the greatest positive impact: on household, personal hygiene and children's products, cosmetics and the like. The current attempt to broadly encircle all chemical users, including manufacturers of products critical to industry, could have the unintended consequence of strangling businesses while doing little to make consumers safer.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kenneth R. Goss". The signature is fluid and cursive, with the first name being the most prominent.

Kenneth R. Goss, Operations Manager  
MWS Wire Industries



Advancing Stewardship, Creating Connections™

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Via e-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the National Association of Chemical Distributors (NACD), I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

NACD is international association of 400 chemical distributors and their supply-chain partners. NACD represents more than 85% of the chemical distribution capacity in the nation and 90% of the industry's gross revenue. Members of NACD operate in every region of the country through approximately 1500 facilities. As leaders in their communities, NACD members are predominantly small regional businesses. The typical member has 26 employees and \$26 million in annual sales.

NACD members meet the highest standards in safety and performance through mandatory participation in Responsible Distribution, NACD's third-party verified environmental, health, safety, and security (EHS&S) program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations. Through Responsible Distribution, NACD members have achieved a strong safety record. Member companies' safety rating is 80 percent better than non-member companies in the Chemical & Allied Merchant Wholesale Industry and more than twice as good as all manufacturing combined.

As a member of the Green Chemistry Alliance (GCA), NACD appreciates the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective chemicals management system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program in order to determine what works and does not work and to make adjustments accordingly. However, beyond this, NACD believes that the DTSC is proposing a regulatory scheme far in excess of what is necessary to conduct the initial phase. NACD, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

NACD is gravely concerned that the Safer Consumer Product Alternatives Regulation as proposed falls well short of meeting the practical, meaningful and legally defensible objectives that DTSC Director Raphael set out when she was appointed to implement this monumental initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879 and SB 509, 2008). The intent of the underlying statute is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

Regulatory uncertainty is one of NACD's most serious concerns about the proposed regulation. As currently drafted, the proposal gives the DTSC unprecedented latitude to implement the program, providing the Department with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply. The current proposal would establish an all-encompassing program that far exceeds the more modest intent of a practical approach. Indeed, in addition to everyday consumer products, virtually all commercially available products and their packaging will be subject to the regulation.

Because this entire regulatory program builds off of each of the prior regulatory actions, it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the preceding actions are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. This piecemeal approach to addressing concerns only exacerbates the tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute, NACD, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on ***exposure*** and ***hazard***, and it ***must avoid duplication and conflicting regulatory requirements***.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports a two-step approach that begins with "chemicals under consideration" and then proceeds to "chemicals of concern." In this regard, NACD concurs with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next craft a manageable process focusing on chemicals that exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by the U.S. Environmental Protection Agency (EPA) and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

It is difficult to reconcile the costs and complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would result in exorbitant costs to all entities doing business in California and would necessitate a huge new government program with a substantial budget requirement. This would only exacerbate California's economic and budgetary challenges.

To date, DTSC has failed to clearly identify potential compliance costs for businesses and individuals, the number of businesses impacted, the number of small businesses that will be impacted, nor the number of businesses and jobs that will be created or eliminated as a result of the regulation. This is unconscionable for such a far-reaching regulation, particularly in a weak economy.

For these reasons, NACD urges the DTSC to delay implementation of the Safer Consumer Products Regulations until a clearer and more reasonable regulatory approach is developed and a more thorough assessment of the economic impacts is completed.

Thank you for the opportunity to comment on this issue. NACD appreciates your consideration of our concerns. If you have any questions or need additional information, please feel free to contact me.

Sincerely,



Jennifer C. Gibson  
Vice President, Regulatory Affairs  
NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS  
1555 Wilson Boulevard, Suite 700  
Arlington, VA 22209  
(703)527-6223

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



National Electrical Manufacturers Association

Representing Electrical and Medical  
Imaging Equipment Manufacturers  
[www.nema.org](http://www.nema.org)

## SUBMITTED BY EMAIL

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**RE: NEMA Comments on Proposed Regulation for Safer Consumer Products - Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04)**

Dear Ms. Von Burg:

The National Electrical Manufacturers Association (NEMA) is the principal trade association representing the interests of the US electrical products industry.<sup>1</sup> NEMA members have more than 120 facilities (headquarters, manufacturing, research, sales or distribution offices) in California and are a significant contributor to California's manufacturing and technology sector.

NEMA appreciates the opportunity to respond to the proposed Safer Consumer Product Alternatives Regulation issued by the Department of Toxic Substances Control ("Department" or "DTSC") in July 2012. We appreciate the considerable effort DTSC continues to invest in developing an efficient and effective regulatory system for hazardous chemicals, as authorized by the underlying California statutes. The Department's announced intention to limit the scope of the program initially to five Priority Products is a step in the right direction.

Overall, however, NEMA continues to view this unprecedented state regulation with alarm as it lacks focus and places virtually no boundaries on the State's discretion to regulate innumerable substances in an untold number of products. We are most concerned with the absence of scientific rigor at key decision points and insufficient emphasis on controlling actual risks to human health and the environment, rather than simply reacting to the presence of potentially hazardous chemicals. In addition, the sheer breadth of the rule and its provisions remains overwhelming – the program **starts with** an initial roster of 1200 Chemicals of Concern and the regulation provides that DTSC may add chemicals that meet only one of 16 factors. The department may then consider 28 factors set out in the rule to determine "Priority Products." In tandem, these provisions grant DTSC extraordinary latitude in selecting product/chemical combinations as a priority product.

Some of NEMA's other concerns with the proposed rule include the following.

---

<sup>1</sup> See [www.nema.org](http://www.nema.org)

- Given the scope, complexity, and likely compliance costs imposed by the system described in the proposal, NEMA questions whether it will generate benefits in terms of improved health and environmental safety that are anywhere near commensurate. Costs will be incurred not just by manufacturers but also by California taxpayers forced to fund a huge new government program with a substantial budget requirement.
- The lists cited in Article 2 as the basis for selecting Chemicals of Concern are not presented in proper context. For example, Category 1; Endocrine Disruptors is only a working list that offers no conclusions on adverse impact. Therefore the listed chemicals may or may not be true endocrine disruptors. The scientific rigor underlying these varied sources no doubt ranges considerably, and some organizations define concepts such as “carcinogenicity” differently. It is thus inappropriate to combine many disparate lists without distinction or qualification as the basis for target substances in this rule.
- Section 69506 of the proposed rule provides that DTSC will adopt regulatory responses that *“maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.”* It also requires that when selecting regulatory responses, the Department shall give preference to responses *“providing the greatest level of inherent protection,”* where ‘inherent protection’ is defined to mean *“avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls.”* NEMA believes these provisions may conflict with the statutory provision in HSC Section 25253, where the legislature established the standard for evaluating COCs in consumer products and their potential alternatives *“to determine how best to limit exposure or to reduce the level of hazard”* posed by a COC. This is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection.
- Parties responsible for Priority Products will be required to conduct Alternatives Assessments (AA) and submit preliminary and final reports to DTSC within a narrow timeframe. This will undoubtedly be a complicated and costly effort that will impose an especially heavy burden on small and medium sized enterprises. The Department notes in the Initial Statement of Reasons document that it conducted an economic impact analysis in accordance with Government Code sec. 11346.3(b).<sup>2</sup> The analysis is limited to three short paragraphs and contains no mention of expected industry compliance costs and their impact on regulated parties – presumably because this metric is not specifically required by this section of the California Code. This is regrettable since the mission and scope of the regulation clearly will force numerous companies to take action and incur expenses. NEMA strongly urges DTSC to provide a more substantive assessment of the costs and benefits of this proposed rule.
- The rule now contains a “Threshold Exemption” that can serve to waive the AA requirement on for some manufacturers, but it is unclear how the threshold level will be determined. Will there be a scientific process? DTSC will evidently set thresholds case-by-case, but it is not a risk-based process.

---

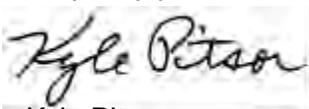
<sup>2</sup> Department Reference Number: R-2011-02 - Office of Administrative Law Notice File Number: Z-2012-0717-04, pg. 4

- Alternatives Assessments also include an “Economic Impacts” component. Responsible parties must “*evaluate and compare the economic impacts of the Priority Product and the alternatives.*” If the outcome of the comparison supports retaining the priority product, the responsible party must “*take into account **all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered***” (emphasis added). This is so broad as to be unworkable. It is unclear how any manufacturer could even estimate all the factors involved. Furthermore, there is insufficient agreement on the methodologies for producing useful, reproducible results – which in any event will only be estimates.
- § 69506.8 of the rule describes End-of-Life Management Requirements as one of the regulatory responses available to the state under the rule. This regulatory option would involve a “Comprehensive Product Stewardship Plan” that includes, among other elements, “*Anticipated resources needed to implement and sustain the plan, including identification of any third-party product stewardship organization **collecting and administering a fee to fund the stewardship program***” [Subsec. (a)(2)(A)6, emphasis added]. This provision, while well meaning, fails to comply with the state action doctrine and is therefore insufficient to authorize the use of a fee by manufacturers to fund a product stewardship program. Any effort by manufacturers to do so would risk violation of federal antitrust regulations.
- The proposal as currently drafted threatens vital intellectual property that engenders innovation, requiring that manufacturers submit more information than is necessary and providing absolute discretion to the Department to make decisions about trade secret claims.

In summary, NEMA generally concurs with the recommendation consistently set forth by the Green Chemistry Alliance that DTSC consider a more focused program, with emphasis on the substances in consumer products that pose true risks for human health and the environment based on hazard, exposure and the likelihood of harm.<sup>3</sup> We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

If you have questions about these comments or wish to discuss our positions further, please contact Mark A. Kohorst of my staff at 703-841-3249 or [mar\\_kohorst@nema.org](mailto:mar_kohorst@nema.org). Thank you again for your consideration and willingness to consider the concerns of regulated parties.

Very truly yours,



Kyle Pitsor  
Vice President, Government Relations

---

<sup>3</sup> See [www.greenchemistryalliance.org](http://www.greenchemistryalliance.org)



## NATIONAL SHOOTING SPORTS FOUNDATION, INC.

11 Mile Hill Road • Newtown, CT 06470-2359 • Tel (203) 426-1320 • Fax (203) 426-7182 • [www.nssf.org](http://www.nssf.org)

**JAKE McGUIGAN**  
DIRECTOR,  
GOVERNMENT RELATIONS

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives  
Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22  
of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

The National Shooting Sports Foundation ("NSSF") is the trade association for America's firearms, ammunition, hunting and recreational shooting sports industry. Its mission is to promote, protect and preserve hunting and the shooting sports. NSSF has a membership of more than 7,000 manufacturers, distributors, firearms retailers, shooting ranges, and sportsmen's organizations. Our manufacturer members make the firearms used by law-abiding California sportsmen, the U.S. military and law enforcement agencies throughout the state.

On behalf of NSSF, I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

The long-standing firearms industry is a proud part of California history yet continues to be targeted with legislation and regulations that infringes on their ability to do business. Many manufacturers in the state have been courted by firearm-friendly states and offered tax incentives and economic benefits to relocate. However, these companies have rebuked these offers in order to still be a part of the California business environment.

The firearms industry has contributed over \$3.6 billion in economic activity to California in 2011, employs more than 10,800 people in the state and generates an additional 4,700 jobs in supplier industries. In these difficult economic times, the firearms industry is still one of the few industries that has grown its profits while also contributing increased tax revenues to the state (to the tune of \$251 million). The firearms business is a highly regulated entity on both the state and federal level. It is unfortunate that precious time is focused on regulations which will severely impact our businesses operating and selling lawful products throughout the state.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

NSSF is pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support.

The firearms industry is already subject to complying with federal standards with respect to its manufacturing process and the different chemical levels it is allowed to employ. Creating a different set of standards will create confusion and make it almost impossible to comply with. The duplicative nature of the regulations could cause situations where not only could companies not manufacture certain products in the state, but also many of our members will not be able to sell into the state.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety that it is likely supposed to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement not to mention that many of the standards have already been set in place by federal regulators.

NSSF believes that the flexibility that the proposed regulations offers the Department with respect to implementing the program and developing *de minimis* levels could be useful for industries that already have to comply with federal standards. The Department could use this flexibility to develop exemptions based upon already derived federal levels. The exemptions could allow for a much smoother and efficient process for many of the already highly regulated industries. America's firearm and ammunition manufacturers have a long and proud history of supporting science-based results whether dealing with wildlife management or the manufacturing of our products. This concept has been championed by our industry, and we will continue to aggressively support science based steps and we believe that the Department should do so as well when crafting regulations. The current proposal would establish an all-encompassing program that seems to exceed the original intent. Not only will our major products be impacted, but also the very packaging we use to market and sell the products.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

Ms. Krysia Von Burg

October 11, 2012

Page 3 of 3

As an industry we are extremely disappointed that the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008). The regulations seem based more on politics and threats of litigation than science. The proposed regulations will only do more harm to the California business environment than increasing public safety.

The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

NSSF, representing hunters and sportsmen organizations around the nation, takes great pride in supporting science-based research and regulations. The hunters and shooters that we represent are the largest financial supporters of conservation programs throughout the United States. The industry is committed and understands, perhaps better than anyone else, the importance of conserving resources and protecting our environment.

The financial burden that is created by these regulations and others makes it increasingly more difficult for manufacturers to continue their livelihood, create jobs and tax revenue for the state.

We appreciate your consideration of our concerns. For further information or questions, please contact our legislative advocate, Kathryn Lynch, at (916) 443-0202.

Thank you!

Sincerely,



Jake McGuigan

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



1773 T Street, N.W., Washington, DC 20009

(202) 223-0101, Fax (202) 223-0250

[www.NaturalProductsAssoc.org](http://www.NaturalProductsAssoc.org)

October 11, 2012

Krysia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

RE: Safer Consumer Product proposed regulations: California Regulatory Notice Register (Z-2012-0717-04).

The Natural Products Association (NPA) is submitting this letter as general comment to the Safer Consumer Product proposed regulations: California Regulatory Notice Register (Z-2012-0717-04). NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of nutritional foods and natural products. The NPA is a non-profit 501(c)(6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers and we build strong markets to fuel industry growth. We are the oldest and largest trade association in the natural products industry representing over 1,900 members accounting for over 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA is concerned about the detrimental impact that the regulations as written will have on association members and the natural products industry as a whole. The comments below outline our main concerns with the regulations and offer our suggestions for how they can be improved. Thank you very much for the opportunity to comment.

The petition process included in the regulations allows persons to circumvent the intended careful, linear DTSC process based on a neutral, agency evaluation of priorities. What is to stop 100 petitions requesting additional priority products from being filed immediately? This could in effect just reopen the rule-making process. Also, the regulated community will step back to the very “product by product” and “chemical by chemical” chaotic regulatory process the Green Chemistry Rules aim to preempt. Petitions to add priority products or chemicals of concern can be filed for any reason, including illegitimate reasons, such as: to attack the reputation of competitor products; to create an adverse public record; or the result of misinformation or sensationalism in the press. This process would derail the limited approach DTSC now advocates.

NPA recommends that DTSC consider suspending the petition process to add priority products or chemicals of concern for 5–7 years to allow the DTSC ordered priorities and process to unfold. NPA would also recommend that petitioners be required to document technical or scientific qualifications pertinent to the subject of the petition as well as certify (perhaps under penalty of perjury) that the petitioner has no direct personal financial stake in the outcome of the petition process. This would tend to limit petitions to governmental authorities, trade associations, collective bargaining units, established non-profits and other collective organizations where vetted, mainstream positions are more likely to be advocated.

The retailer burdens included in the regulations are unreasonably heavy and inevitably will lead to negative consequences. First, not all retailers can continuously monitor websites for priority products and other proceedings. Many retailers do not have the financial resources, personnel or the complex background skills to conduct such monitoring. Second, if DTSC forces retailers to identify themselves as sellers of priority products, we predict the vast majority of retailers simply will refuse to sell the products. Thus, DTSC’s designation of a priority product is effectively an immediate product sales ban. Few retailers will a) absorb the burden of seeking legal advice on their obligations under this new law; b) file with DTSC and monitor developments on a priority product; c) have the resources to implement DTSC’s

determinations (e.g., product recalls or quarantines); or d) conduct an alternatives assessment. Thus, even before anyone begins an alternatives assessment, the priority product may effectively disappear from many retailer shelves resulting in a de facto product ban. Consumers may well be denied safe, lawful and appropriate products simply because retailers cannot and will not take on the burdens of the law.

NPA recommends that DTSC suspend retailer duties of any sort until the alternatives assessment process is complete. Retailers should never be charged with conducting alternatives assessment. If products are later banned, or recalled, DTSC can send notices to the public in an effort to cover all such items.

The alternatives analysis process is very complex, cumbersome, costly and almost certainly beyond the financial and technical ability of many small- to medium-sized manufacturers. Again, the likely outcome is that a priority product will be withdrawn from the market, as the economic and other costs would be prohibitive. The notion that similar parties can band together to have “group alternative analyses” is likely to be unworkable. First, competitors all have intellectual property and other confidential information that they will be loathe to share with each other in support of a collective effort. Second, most competitors distinguish their products, meaning the same products will not have uniform properties, making collective assessments difficult, prone to inaccuracies as they relate to any one product, or impossible. “Free rider” problems will arise when only some parties will fund an alternatives analysis, but many more can rely on the results. Again, the likely result of these difficulties will be withdrawal of the product before there is any proof the product is anything other than safe, lawful, and of benefit to consumers.

NPA recommends a streamlined alternatives analysis option for small- to medium-sized manufacturers or other businesses, perhaps involving a form that could be completed by a non-expert based on available information to the party.

Overall, the regulations as currently written are so burdensome on both DTSC and the regulated community that it begs the question of whether industry can submit, and DTSC can evaluate, alternatives assessments in a timely manner. This inherent complexity renders the rule inoperative from day one in practical effect. Why not start with a small pilot? DTSC could evaluate one product for just one chemical of concern to give an example of how the rules actually work before implementing the full program.

NPA appreciates your consideration of our comments.

A handwritten signature in black ink that reads "Cara Welch". The signature is written in a cursive, flowing style.

Cara Welch, Ph.D.

Sr. Vice President, Scientific & Regulatory Affairs

Natural Products Association

## GCREgs@DTSC

---

**From:** Jane Newman <janewashere@hotmail.com>  
**Sent:** Tuesday, October 02, 2012 8:08 AM  
**To:** GCREgs@DTSC  
**Subject:** consumer protection

We need legislation to protect us from dangerous chemicals in industrial use. If Europe can do this, so can we.  
Thanks-Jane Newman

**From:** peterbnewman <peterbnewman@marincounty.net>  
**Sent:** Sunday, October 07, 2012 5:45 PM  
**To:** GCREgs@DTSC  
**Subject:** public comment re chemicals of concern plan

Dear California Department of Toxic Substances Control --

First off, I would like to know if this is the correct medium (email) and location ([gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)) to make comment on your plan re "chemicals of concern"?

I could not find anything at your site that clearly states where and how to make comment -- only a notice that the comment period had been extended to October 11th, and the above email address at the end of that page.

If this is the correct way/place, hooray.

If not, please forward this to who/how/where it should have gone.

Here are my comments:

1) I am disappointed that your site does not provide more-useful information to the new visitor (me) -- and that there is no clear place to make comment on current issues under consideration that gives me the impression that you do not really welcome public comment

2) So to validate my comments I will first state my bona fides: I am not chemically sensitive (to my knowledge), but I did suffer a cancer (RCC) 10 years ago that is environmentally-induced -- and is on the rise, and is believed to be chemically-induced.

I also have a degree from UC Berkeley in the sciences, and part of an MBA from SFSU. I am a businessman and also a science nerd and I consider myself both well-informed and fairly reasonable.

I guess I should also say that I own stock in most of the major chemical corporations in this country (via the S&P500), plus I have owned a number of specific companies on and off over the decades -- and currently own about \$100K in various chemical company stocks.

3) Having said that, I want to be quite specific and somewhat harsh in my criticism: The chemical industry has been given a carte blanche to experiment on the unsuspecting American public for 60+ years now. They have added hundreds of thousands of new chemicals to our bodies and our environment. It is long, long past time that they be more-closely regulated -- and one fine place to start is by making them disclose to the public what is in our stuff. Some of us are label-readers and know enough to understand what they may mean. Others are entitled to a crack at protecting themselves even if they are not as well-equipped to understand this material.

Plus, it makes zero sense in the age of information to withhold data that we are entitled to know and that might well be germane to our health. Obviously I believe in capitalism -- but I also hope for the free flow of information that is supposed to make markets efficient and capable of making wise decisions. To accomplish that you must release all possible helpful information.

Additionally, I am aghast and disappointed to find the Democratic leadership of this state easing off on the chemical companies when it is clear that is exactly what the public does not want. We are aware of that there are too many chemicals in our lives -- we need data and disclosure to help us use only the ones we must.

Lastly, although I am not a parent, I am an uncle... I hate the idea that my nephews and nieces will continue to be subject to the largely unregulated chemical experiment that is this industry's standard practice -- and I hate the idea that that generation will suffer even more cancers (or other diseases) if something is not done to stop this assault.

The first step in stopping an assault is to identify the attacker and the weapons -- so please strengthen, not weaken, the plan to fully disclose "chemicals of concern".

Thank-you for your attention to my concerns.

Sincerely,

Peter B. Newman



BTW, I also do not belong to any anti-chemical-industry group -- or any other radical political groups. And I was not encouraged by anyone to write this letter. I read an article in today's SF Chronicle about this plan, and that the comment period had been extended, and I decided to add in my two cents.

Maybe the last thing I should say is that, before finishing at UC Berkeley I was a pre-med student at the Uof Pennsylvania -- where I managed to ace my year-long Chem 101 course final. I was only one of three people in a class of 600 to do that. So, I am not un-familiar with the benefits chemicals have brought to the modern world. But I am also quite clear that the industry has been far too under-regulated. It has long been clear that we absorb chemicals in ways other than solely through food or drugs -- and yet we are far more protected from bad meat or bad drugs while thousands of dangerous, unregulated, and un-checked chemicals wreak their quiet, slow havoc on us and the environment.

And that is coming from a rich white guy who was a third generation corporate kid, and who owns guns. Yeah, I also live in Marin. And I vote Democrat.

This is not about politics -- it is about human (and environmental) health. There is no excuse for hiding the truth from us: not when the results can be so significant.

PBN



*Celebrating 75 Years  
of Energy Efficiency*

**VIA E-MAIL**



October 11, 2012

Ms. Krysia Von Burg  
Regulations Coordinator  
California Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

RE: Comments of the North American Insulation Manufacturers Association (“NAIMA”) on the California Department of Toxic Substances Control’s Proposed Regulation: Safer Consumer Product Alternatives (Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04)

Dear Ms. Von Burg:

## INTRODUCTION

The North American Insulation Manufacturers Association (“NAIMA”) appreciates the opportunity to submit written comments on the California Department of Toxic Substances Control’s (“DTSC”) revised draft regulation entitled “Safer Consumer Product Alternatives.” NAIMA appreciates that DTSC has modified its approach from the first draft. Unfortunately, these modifications did not sufficiently mitigate many of the unnecessary burdens on businesses and California’s economy resulting from the proposed regulations or increase significantly benefits to public health and the environment. The proposed rule as revised could do significant harm to California’s economy.

Most importantly, the revised draft continues to give untested products and substances an undeserved and unmerited pass as acceptable substitutes for thoroughly tested and researched products and substances. DTSC should never assume that untested products or substances are safe; it can frequently be the case that the reason why no data exist on a particular product is that its manufacturers are careful not to generate any data regarding product hazards.

NAIMA is the association for North American manufacturers of fiber glass, rock wool, and slag wool insulation products. NAIMA promotes energy efficiency and environmental preservation through the use of fiber glass, rock wool, and slag wool insulation, and encourages the safe production and use of these materials. NAIMA’s members operate four insulation manufacturing plants in California and also import significant volumes of insulation into the State. Fiber glass insulation products are used widely throughout the State of California. NAIMA’s members’ insulation products are sold at home improvement stores throughout the State and installed by homeowners as weekend do-it-yourself projects. Their products are also installed by professional insulation contractors in both new and existing homes and commercial

buildings. Therefore, the DTSC's revised regulation is highly relevant to NAIMA and its manufacturing members.

#### DTSC's DRAFT RULE FAVORS UNTESTED AND UNPROVEN PRODUCTS

NAIMA is concerned that the revised regulations will be implemented in such a way that replacement materials will be approved for use over listed materials because there is no data on the potential health effects of those replacement materials. Lack of data does not necessarily equate to safe.

Have supposedly "safe substitutes" been tested? There is no scientific data available for many materials and products. Many materials and products have never been reviewed by expert panels such as the International Agency for Research on Cancer ("IARC") and the Department of Health and Human Services ("HHS") to make a decision on whether they present health hazards. For example, IARC and the National Toxicology Program ("NTP") do not even review a substance or product unless there is ample data to evaluate. NTP mandates that substances to be nominated for review possess appropriate background information and relevant data.<sup>1</sup> Similarly, IARC's selection of agents for review requires that published data on the potential carcinogenicity of the agent be available for review.<sup>2</sup>

The necessity of data to form a conclusion or listing is obvious. Yet DTSC seems to have ignored the simple fact that many producers of agents/substances purposefully decide to avoid testing or research on its products/substances. The reason is the likely avoidance of ending up on a list such as the ones relied upon by DTSC. Therefore, DTSC's regulation gives preferential treatment to untested products.

An untested product does not mean it is a safe product.<sup>3</sup> A system wherein untested products are treated as though they are safe and not regulated should not form the basis for a decision on whether a product is banned. DTSC should avoid awarding preferential treatment to a product or substance simply because a particular product's manufacturer has neglected responsible product stewardship and refused or failed to test its product. Indeed, the failure of a particular product or substance to be adequately tested by its manufacturer should be a critical factor in determining that a product is not an acceptable alternative.

Sincerely,



Angus E. Crane  
Executive Vice President, General Counsel

---

<sup>1</sup> Process for Preparation of the Report on Carcinogens, Page 1 (January 3, 2012). <http://ntp.niehs.nih.gov/NTP/RoC/Thirteenth/Process/FinalRoCProcesswithFig.pdf>.

<sup>2</sup> World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans" Volume 99, Some Aromatic Amines, Organic Dyes, and Related Exposures, Page 12 (2010). <http://monographs.iarc.fr/ENG/Monographs/vol99/mono99.pdf>.

<sup>3</sup> J.M.G. Davis, "The need for standardized testing procedures for all products capable of liberating respirable fibres; the example of materials based on cellulose," *British Journal of Industrial Medicine* 1993; 50: 187-190.



October 11, 2012

Via E-Mail

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of  
Division 4.5 of Title 22 of the California Code of Regulations (Z-  
2012-0717-04) (July 2012)

Dear Ms. Von Burg:

The North American Metals Council (NAMC)<sup>1</sup> submits this letter in response to the California Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Alternatives regulations of July 2012. NAMC's comments, similar to our December 29, 2011, comments on a previous draft of this regulation, focus on the proposed process to identify chemicals of concern, which, as we understand it, will then be used to identify priority products for review under the regulations. Because metals, metal compounds, and metal products exhibit unique characteristics it is inappropriate to evaluate them using the general hazard evaluation principles applied to organic chemicals.

As we understand, the regulations would apply to all chemicals that exhibit a hazard trait and that are present in consumer products in California. According to the proposed regulations, hazard traits are defined in Division 4.5, Title 22, California Code of Regulations -- Chapter 54, *Green Chemistry Hazard Traits for California Toxics Information Clearinghouse*. That document includes both environmental persistence and bioaccumulation as hazard traits. As noted in our previous comments, hazard factors for a metal depend on -- among other things -- the specific metal, the form of the metal and/or metal compound, the bioavailability of the metal to particular organisms, and the organism's ability to regulate and/or store the metal. Certain environmental endpoints used to screen, assess, or prioritize organic compounds -- particularly bioaccumulation and persistence -- are not appropriate for assessing the hazard of metals. We urge DTSC to highlight specifically in the

---

<sup>1</sup> NAMC is an unincorporated, not-for-profit group of metals-producing and metals-using associations and companies formed to provide a collective voice for the North American metals industry on science and policy-based issues that affect metals in a generic way.  
{0609.003 / 111 / 00102025.DOC 2}



North American Metals Council

Ms. Kryisia Von Burg  
October 11, 2012  
Page 2

final regulations that metal substances will require specialized review and to reference the U.S. Environmental Protection Agency's (EPA) *Framework for Metals Risk Assessment* as the guideline that DTSC will use in its evaluation of such substances.

NAMC is also concerned with the proposed authorities DTSC has reserved for itself to run this program. With the discretion DTSC has built into the process at multiple decision points, there appears to be little to no opportunity for industry or impacted stakeholders to fully understand what must be done to comply with the regulation. Given that virtually all commercially available products and their packaging will be subject to the regulation, this lack of transparency will likely cause chaos among the regulated community. Indeed, rather than achieving the objective of innovation of safer consumer products, the regulations as proposed will create an unpredictable framework that will increase uncertainty in the business community.

NAMC supports the recommendation by Senator Michael J. Rubio (D-Shafter) to delay these regulations until a more thorough economic impact analysis is available. As previously noted, given that this regulation will impact virtually all products in California, a true sense of the impact to California businesses and communities is essential.

Thank you in advance for your review and consideration of these comments. If you have any questions or require additional information, please contact me at 443-964-4653 or [kroberts@namc.org](mailto:kroberts@namc.org).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Kathleen M. Roberts". The signature is fluid and cursive, written over a light gray background.

Kathleen M. Roberts  
Executive Director  
NAMC

cc: The Honorable Matt Rodriguez, Secretary, CalEPA (via e-mail)  
Miriam Ingenito, Deputy Secretary, CalEPA (via e-mail)  
Kristin Stauffacher, Assistant Secretary, CalEPA (via e-mail)  
Nancy McFadden, Cabinet Secretary, Office of the Governor (via e-mail)  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor (via e-mail)  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor (via e-mail)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor (via e-mail)

## **GCREgs@DTSC**

---

**From:** Kevin O'Brien <kmobrien1@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 9:49 AM  
**To:** GCREgs@DTSC  
**Subject:** dangerous chemicals

**Categories:** Comment

Our family feels strongly that you should follow through on the process to identify, regulate and remove from legal use those 1200 dangerous chemicals identified and included in the state law from 2008. Thank you, Kevin O'Brien

## GCREgs@DTSC

---

**From:** PALMER JR., DONALD G <dp2697@att.com>  
**Sent:** Tuesday, October 02, 2012 12:31 PM  
**To:** GCREgs@DTSC  
**Subject:** Opposed to Proposed SCP Regulations

Dear DTSC,

I write to oppose DTSC's proposed Safer Consumer Products regulations.

The proposed regulations go far beyond the intent of the enabling legislation, both as to the scope of the chemicals of concern to be identified and the compliance obligations required of manufactures, importers, and retailers of consumer products in California. The scope of the regulations are so broad and complex that they risk failing to achieve the objectives of the original legislation - identify dangerous chemicals in consumer products and mitigate exposure to consumers, including the potential use of safer alternatives where feasible. Instead, these regulations focus on potentially thousands of chemicals and literally every form of manufactured product used by consumers in this state, from cars and trucks to household cleaners and everything in between!

The cost of compliance by businesses affected by these regulations is likely to be staggering; indeed, even DTSC could not effectively identify the potential cost impact of these regulations.

As a California resident, consumer, and responsible citizen of this state, I support making consumer products safer for use by consumers. However, I believe the methods chosen by DTSC in this regulation will only lead to confusion, increased costs to businesses and consumers, and simply fail in its mission to get the most dangerous chemicals out of consumer products in the shortest amount of time.

Respectfully,

Donald G. Palmer, Jr., Esq.  




October 11, 2012

**By Electronic Mail**

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**RE: Safer Consumer Products Proposed Regulations**

Dear Ms. Von Burg:

The Personal Care Products Council (Council)<sup>1</sup> is pleased to submit the following comments on California's Safer Consumer Products proposed regulations that were developed by the Department of Toxic Substances Control (DTSC) and publicly released on July 27, 2012. Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in California and throughout the United States, and therefore have a strong interest in the scope and applicability of these regulations.

**INTRODUCTION**

Since the inception of California's Green Chemistry Initiative in May 2007, the Council and its members have engaged California legislators, regulators, non-governmental organizations, and the business and scientific community to provide thoughtful insight, ideas, and comments about Green Chemistry. The Council has hoped to develop a practical and effective regulatory framework that would promote sustainable innovation while making meaningful improvements to the protection of human health and the environment.

---

<sup>1</sup>Based in Washington, D.C., the Council is the leading national trade association representing the \$250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation.

Although the Council objected to many provisions in the draft regulations,<sup>2</sup> released on October 31, 2011, it is evident from the recently released proposed regulations that DTSC addressed some of our concerns and made important modifications. The Council applauds, for example, the removal of the Safe Cosmetics Act as a source for the Chemicals of Concern list; and the elimination of the distinction between “assembled” and “formulated” products; and acknowledges that while the timelines for conducting an alternative analysis remain shorter than what is necessary they are a step in the right direction. Despite positive changes, however, there remains work to make the proposed regulations more effective and less burdensome for the regulated community. Therefore, in this spirit of cooperation, the Council respectfully submits the following comments, both general and specific, in the hopes that DTSC will consider them and make our suggested changes to the regulations before issuing the final regulation.

#### **KEY POINTS**

Below are the primary points that the Council raises:

- 1. OTC Drug Exemption.** OTC drugs, like prescription drugs, are comprehensively regulated by FDA and should be exempt from these regulations.
- 2. Initial List of Chemicals of Concern.** The “list of lists” chemical identification process proposed by DTSC is fundamentally flawed and scientifically indefensible.
- 3. Alternatives Analysis Exemption Threshold.** The proposed solution will create an unnecessary burden on DTSC to set a specific threshold for each chemical of concern in a listed priority product and will lead to burdensome assessments and reformulations based upon trace amounts of a chemical of concern. A reasonable *de minimis* threshold with precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union’s REACH program of 0.1% (1000 ppm) should be established.
- 4. Certified Assessors/Accreditation.** The entire program contained in Article 8 is unnecessary and should be removed.
- 5. Regulatory Duplication.** DTSC must clarify precisely when a regulated product is exempt and when it is not. Otherwise this exemption will have no utility.

---

<sup>2</sup> Please refer to the Council’s previously submitted comments, which these comments incorporate by reference.

## **GENERAL COMMENTS**

### **SMALL BUSINESS IMPACTS**

As with the draft regulations, the proposed regulations do not address the significant adverse impacts that this regulation will have on small and mid-sized businesses.

The California Government Code recognizes the potential for small businesses to be adversely impacted by complex regulations promulgated by state agencies:

*The complexity and lack of clarity in many regulations put small businesses, which do not have the resources to hire experts to assist them, at a distinct disadvantage.* (California Government Code, §11340.)

In order to address this concern, the Government Code goes on to require state agencies, in developing regulations, to assess ways to ameliorate adverse impacts to small business:

*Every agency subject to this chapter shall prepare, submit to the office with the notice of the proposed action as described in Section 11346.5, and make available to the public upon request, all of the following...(5)(B) A description of reasonable alternatives to the regulation that would lessen any adverse impact on small business and the agency's reasons for rejecting those alternatives.* (California Government Code, §11346.2.)

DTSC admits in its Initial Statement of Reasons that the regulations will disproportionately impact small business. Yet despite being required to submit to the Office of Administrative Law alternatives to the regulations that would lessen the impact to small businesses, DTSC suggests no alternatives. It excuses its inaction by stating in its Economic and Fiscal Impact Statement that it cannot accurately assess impacts to businesses until *after* the regulations are actually implemented. It then claims that, even if it could assess the impacts, the underlying statute prevents it from being able to “apply these regulations in a differential manner based upon the size of a business”. In other words, the regulations are a mystery even to DTSC.

DTSC does state that it will address the disproportionate impacts, not in the regulations, but only later, in an Alternatives Analyses guidance document, which presumably would be promulgated after the regulations were final. This is insufficient process and does not comply with the dictates set forth in the Government Code.

DTSC recognizes that the impacts will be disproportionate to small businesses, and it should therefore attempt to assess those impacts and offer reasonable alternatives.

The State of California has recognized the importance of small business to the health of the economy and as a driver of job growth. It is critically important that DTSC “level the playing field” for small businesses that lack the resources of a larger company and, therefore, will have greater difficulty in complying with the regulation. As such, the Council strongly urges DTSC to develop provisions providing flexibility for small and mid-sized businesses – perhaps coordinating with the state’s Small Business Advocate or the SBA Office of Advocacy’s Regional Office – as a way to sustain and protect the viability of this important segment of California’s economy. At a minimum, DTSC must adequately explain to the Office of Administrative Law – as required by the Government Code – what alternatives are available to small businesses that will help address the adverse impacts of the regulations.

#### **REGULATIONS AS TECHNICAL BARRIER TO TRADE**

The Agreement on Technical Barriers to Trade is an international treaty administered by the World Trade Organization (WTO). The Agreement exists to ensure that technical regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade. Because the proposed regulations create a local review and reformulation process not legally applicable outside the boundaries of California, and because this process is not linked directly to safety assessments of products but is predicated upon merely speculative harm to consumers, it is not well tethered to national policy concerns and could be construed as a protectionist measure favoring California companies with access to local regulators.. Presumably, DTSC has notified WTO about these draft regulations. Notification will allow the WTO, in turn, to notify member countries of the regulation, so that they can submit official comments in accordance with the TBT agreement.

This concern is especially important as many consumer products placed into the stream of commerce in California are manufactured outside the United States, and it is likely that – unless DTSC has explicitly informed WTO of this rulemaking – most member countries of the WTO will be unaware that the public comment period in California is underway.

The Council asks DTSC to confirm publicly if and when it notified WTO about these draft regulations.

#### **SPECIFIC COMMENTS**

The Council also offers these specific comments to the individual provisions of the draft regulations:

#### **ARTICLE 1: GENERAL**

##### **§69501: Purpose and Applicability**

##### **Subparagraph (b) - PAGE 4**

## **EXEMPT OTC DRUGS**

DTSC claims that the scope of the consumer products subject to the propose regulation is “consistent with existing statutory reach” and that exempting any other consumer products “would not be in line with the intent and purpose of the authorizing legislation.” DTSC concludes that any additional exemptions beyond those set out in statute “would impermissibly shrink the scope of consumer products that are subject to the regulations.”<sup>3</sup>

We respectfully disagree. The regulations are intended to cover consumer products not already subject to a comprehensive regulatory scheme, such as with over-the-counter (OTC) drugs. By not exempting OTC drugs, DTSC risks implementing a regulatory response that would run counter to the mandates of the Federal Food and Drug Administration (FDA). Prescription drugs and medical devices are exempt from the green chemistry regulation for precisely the same reasons that OTC drugs should exempt.

Importantly, DTSC should consider that OTC drugs are subject to extensive regulation with respect to labeling and ingredients by FDA. Topical OTC’s must either conform strictly with monograph provisions regarding active content and labeling, or they must be approved individually through FDA’s pre-market drug approval process. Any attempt to alter either labeling or ingredients from approved forms would be met with a significant pre-emption risk.

Clearly, DTSC should recognize that it does not possess the jurisdictional, functional or technical expertise to regulate OTC drugs under the Federal Food, Drug and Cosmetic Act (FFDCA) and that in the United States, FDA is the sole agency responsible for determining which active ingredients are allowed for OTC use. Moreover, FDA is also responsible for evaluating the safety and efficacy of all active ingredients listed in individual OTC drug monographs and is currently evaluating the efficacy and safety of numerous active ingredients listed under several OTC tentative final monographs under a public rulemaking process which DTSC can contribute comments to.

DTSC’s inclusion of OTC drug ingredients and products under the proposed regulation would only create havoc and confusion regarding how OTC drug products and active ingredients are regulated in the United States. Moreover, this action would directly clash with the established process for determining the Generally Regarded as Safe and Effective (GRASE) status of OTC active ingredients under the FFDCA. In addition, the inclusion of new alternative OTC Drug ingredients that are not currently listed for use by FDA under an OTC drug monographs would be illegal and require FDA premarket approval under FDA’s New Drug Application (NDA) or Time and Extent process. Such inclusions generally require extensive

---

<sup>3</sup> Initial Statement of Reasons, page 11.

safety, clinical and performance tests that require FDA approval, take years to conduct and cost tens of millions of dollars.

In addition, DTSC must realize that FDA OTC monographs may have different performance criteria or labeling requirements for OTC drugs used by consumers versus those used by Industrial & Institutional (I&I) facilities such as hospitals and food processing and establishment facilities. It is currently unclear whether OTC drugs targeted for human use in hospitals and food processing establishments would be subject to the proposed rule. Such establishments should also be exempted from regulation.

DTSC's inclusion of OTC drug ingredient and products under the proposed regulation would undermine FDA's OTC drug review process, potentially adversely impact public health, and, at minimum, create uncertainty with regard the marketing and availability of important non-prescription health care products in the United States.

It would be disingenuous for DTSC to argue that the "regulatory duplication" provision of the regulations will allow manufacturers of OTC drugs to make the case for being excluded from the regulation. Regulatory duplication is not even considered until the "regulatory response" stage – well after manufacturers have incurred the cost and expense of conducting an alternatives analysis and responding to the regulatory process. This would be a significant waste of time and resources.

Based on the foregoing, the Council strongly urges DTSC to exempt OTC drugs from the scope of these regulations.

#### **§69501.1: Definitions**

##### **Subparagraph (a)(19)(A)(1): "Chemical" – PAGE 8**

The definition of "chemical" contains an indirect reference to traces and precursors. It identifies not only the chemical in question, but also related chemistries – even if only distantly related – which presumes the same hazards of all loosely related chemistries with no basis for the assumption. This provision has the potential to give DTSC unlimited authority to regulate virtually any ingredient irrespective of its status as a chemical of concern. At the same time, it provides no real guidance to the manufacturer on what exactly it needs to assess. It appears to be an attempt to sweep within the ambit of the regulation everything that conceivably *might* be of interest rather than focusing agency and industry attention on the limited subset of chemicals that should be of interest, based on appropriate scientific evidence.

The Council recommends DTSC clarify and narrow the definition of "chemical". A more useful definition would be to define "chemical" as a substance or a mixture as defined by the UN GHS for these two terms.

**Substance** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

**Mixture** means a mixture or solution of two or more substances which do not react.

#### **Subparagraph (a)(38): “Legal Requirements” – PAGE 10**

The Council requests that the definition of “legal requirements” be amended to include not just product packaging, but also *labeling*.

#### **Subparagraph (a)(52): “Reliable Information” – PAGE 12**

The definition of “reliable information” should be modified to focus on the weight of scientific evidence. Single studies published in peer-review journals often conclude there exists suggestive evidence of a specific hazard however are not conclusive by themselves. It is only through evaluation of the full weight of evidence that a clear understanding of a causal relationship between exposure to a substance and an outcome of concern can be conclusively determined. It’s only through scientific debate and exchange that these conclusive results emerge. DTSC must outline how a weight of evidence approach will be followed throughout the chemical and product prioritization process as well as through evaluation of the alternatives assessment and ultimately in determining the regulatory response.

Also, much as scientific information filed with FDA may qualify as “reliable information”, so to should appropriately-vetted industry data.

#### **Subparagraph (a)(58): “Sensitive Subpopulations” – PAGE 13**

The definition of “sensitive subpopulation” refers not just to subgroups that comprise a meaningful portion of the population, but also “individuals with a history of illness” and “workers”. This is exceedingly broad and essentially makes the term so expansive as to be moot. The Council recommends deleting this reference to individuals with a history of illness (or modifying the term to conform with DTSC’s intent to cover only those “serious” or “chronic” illness affecting a meaningful portion of the population). DTSC should also delete all references to workers (whose health is regulated by Cal OSHA, as discussed later in these comments), before finalizing the regulation.

### **ARTICLE 2: CHEMICALS OF CONCERN IDENTIFICATION PROCESS**

#### **§69502.2: Chemicals of Concern Identification**

##### **Subparagraph (a)(1) and (a)(2): Initial Chemicals of Concern List**

The current “list of lists” approach is fundamentally flawed and must be changed. This is perhaps the most important and overriding problem with the proposed “process” established in the regulation.

None of the lists identified by DTSC in the proposed regulation were intended to serve as an authoritative source for this type of legislation, and each has vastly different criteria for listing a chemical. Reliance upon these lists is not a science-based approach. It offers no opportunity to remove a chemical listed elsewhere, and it flies in the face of a robust scientific process that would subject each listed chemical to exhaustive review before listing.

These lists were each compiled and reviewed for different reasons, and for different purposes, and never were these chemicals reviewed for their presence in any category of product and any resulting human exposure. Additionally, this approach virtually eliminates any opportunity to amend the list of chemicals of concern through removal of a COC as these lists have significant overlap and thus removal from only one of the lists will not remove the ingredient from the chemicals of concern list, even if evidence is presented to support its removal. This approach makes it near impossible to create a list of true chemicals of concern that meet the criteria as established by California and distracts from a focus on reducing the chemicals which have true need for reduction.

Instead, the Council recommends implementing a process that lists chemicals one at a time, allowing interested parties to submit scientific information and arguments relating to an individual chemical. DTSC could start with an initial list of chemicals with well-established hazards (say, CMRs), then gradually add to it, rather than trying to list everything at once. California already has such a process in place. The Office of Environmental Health Hazard Assessment (OEHHA), using the “authoritative bodies” mechanism under Proposition 65, notices chemicals of concern, and accepts public comment, before final listing. A similar process, which would be far more equitable, could be used with green chemistry. Note that the Prop 65 listing process, which is more rigorous, only leads to the application of warning statements on products or where they are sold. A process that compels the reformulation of products at expense to producers and with risk to consumer benefit should surely be at least as rigorous.

Based on the foregoing, the Council strongly recommends eliminating the “list of lists” approach for a more scientifically valid and defensible approach to chemical identification.

**Subparagraph (a)(1)(c): Endocrine Disruptors**

Particularly problematic is the inclusion of the “Category 1 endocrine disruptors” identified by the European Commission. First, it is only a “working list” in need of continued scientific rigor. The list was not created by an authoritative body and there is no conclusion on adverse impact. The list itself is

titled as “...substances for further evaluation...” further demonstrating it is not a fully vetted complete list for consideration by regulatory agencies during rulemaking and thus it should not be included in creating a list of chemicals of concern. That determination indicates doubt about whether the chemicals listed are appropriate for formal regulation.

The argument against the inclusion of the Category 1 endocrine disruptors list is further buttressed by the focus of the World Health Organization (“WHO”). WHO defines “endocrine disruption” as a material that must cause adverse effects in the intact organism, its progeny, or a sub population, and specifies what constitutes an adverse effect. The data used to generate the EU Commission list was generated using in vitro data. So by the WHO definition, the Commission data set is inadequate to establish “endocrine disruption”. Thus, it’s an abuse of discretion for DTSC to include this data set within its Chemicals of Concern list.

It is well known that endocrine disruption is a nascent science without strong scientific consensus. Endocrine activity is not a distinct toxicological end point per se, but rather a measure of a chemical’s ability to interact with components of the endocrine system. Evidence of interaction with endocrine processes does not necessarily give rise to adverse effects.

The Council urges that endocrine disruptors be removed from the lists.

### **ARTICLE 3: CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS**

As an initial matter, the Council strongly recommends that DTSC allow the use of opinions from recognized cosmetic authoritative bodies (e.g., the Cosmetic Ingredient Review<sup>4</sup>, and Scientific Committee on Consumer Safety) when identifying COCs in priority products. If a human health and safety concern is the motivation for identifying a COC in a cosmetic product, then conclusions from CIR and SCCS should necessarily be considered and possibly used to justify their inclusion or removal. In

---

<sup>4</sup>The Cosmetic Ingredient Review (CIR) was formally established in 1976. All personal care product ingredients, except those reviewed by FDA (i.e., color additives, food ingredients, drug inactive ingredients), are prioritized by CIR using such factors as volume of use, structure-activity relationship, and inclusion on lists of suspect chemicals. The CIR Expert Panel, which is the decision making body of CIR, is an independent, independently-funded, panel of scientific experts with U.S. Food and Drug Administration officials and a representative of the Consumer Federation of America participating as liaison members. The Expert Panel is prohibited from direct and indirect consulting with any personal care product company, and the deliberations of the CIR Expert Panel, and all information made available to that Panel, are open to the public.

other words, if CIR makes a conclusion about an ingredient as to human safety, then that information should be viewed as authoritative and conclusive in the prioritization phase of the process.

### **§69503: General**

#### **Subparagraph (b): Information – PAGE 25**

Subparagraph (b) states that DTSC is *not limited* to using the information reviewed under 69501.4 to perform its duties of prioritizing products for regulation. This seems to undercut the focus on “reliable information” in the prior sections and removes any clear guidance gained by properly defining reliable information. If DTSC can use any information to prioritize products, as stated in this subparagraph, then any previous reference to reliable information is moot.

### **§69503.2: Priority Product Prioritization Factors**

#### **Subparagraph (a)(1)(B)(4)(b)(iii): “Worker Exposure” – PAGE 27**

Worker exposure is within the exclusive jurisdictional purview of California OSHA, which occupies the field in ensuring and addressing exposures in the workplace. This subparagraph should be deleted in its entirety, as well as any other references in the regulation to “workers” “worker exposure” or “workplace”.

### **§69503.4: Process to Evaluate Products Using Prioritization Factors**

#### **Subparagraph (e): Initial Priority Product List – PAGE 30**

Under the proposed regulation, the initial list of Priority Products shall not contain more than five products. This is a more manageable approach because it focuses attention on a limited number of products. It does not, however, limit the number of priority products that may be designated in subsequent three-year work plan cycles. Also, it does not limit the number of chemicals of concern that may be identified in a product. Additionally, it does not limit the scope of what those product categories could encompass. For example, if one of the five products was “personal care products” this would include thousands of products under one umbrella. The current proposal gives no guidance as to how the products will be classified and thus creates further ambiguity.

The Council recommends continuing to identify only a handful of priority products – no more than five – in all subsequent work plans/priority product lists.

### **§69503.5: Alternative Analysis Threshold Exemption**

Although the Council applauds the removal of the 0.01% *de minimis* level from the draft regulations, DTSC has replaced it with an Alternative Analysis “trigger” threshold that is totally discretionary to the agency, limited only by available analytical methodology. It is, therefore, subject to political pressure rather than being strictly science-based, or may be measurable only by advanced or even experimental techniques not broadly available to the regulated community. The proposed alternative analysis threshold exemption will also leave the regulated community confused as to their obligations and forcing them to incur unnecessary expense testing to detect trace levels of chemicals that have no bearing on objective safety.

Labeling this mechanism as a triggering threshold for conducting an alternatives analysis, rather than a *de minimis* level, is an attempt to avoid the reality that DTSC should comply with all other federal and international legal authorities that have set a 0.1% *de minimis*. Despite the new label, however, it is essentially a *de minimis* level. A default *de minimis* levels provides certainty and predictability to the regulated community allowing them to fully understand their compliance responsibilities. And, as such, setting a uniform threshold amount for all chemicals at 0.1% would make the proposed regulations consistent with a majority of state, federal and international regulations, including the European Union’s R.E.A.C.H. framework, which employs a 0.1% by weight *de minimis* threshold for reporting as well as the European Cosmetics Directive which includes a 0.1% *de minimis* level for over 1,300 carcinogens and reproductive toxicants.

#### **ARTICLE 4: PETITION PROCESS FOR IDENTIFICATION AND PRIORITIZATION OF CHEMICALS AND PRODUCTS**

##### **§ 69504. Applicability and Petition Contents**

Given the proposed size of the Initial Chemical of Concern list, and the potential universe of priority products (particularly in subsequent work plans), it seems unnecessary to immediately allow petitions to add to either list. DTSC should disallow any entity or member of the public to request additions to the list *until such time* as each of the initial chemicals of concern and priority products has been addressed.

The Council applauds DTSC for including a petition process that allows chemicals and priority products to be *removed* from (not just added to) the appropriate lists. However, as the only criteria right now seems to be a chemical’s presence on one of these lists, DTSC will need to provide other criteria, beyond appearance on a list, that will be considered. In addition, the petition process should extend to chemicals on the initial chemicals of concern list. Under subparagraph (b) of this section, DTSC prohibits a petitioner from removing a chemical of concern from the initial list of chemicals unless it no longer appears on any of the lists. Given our previously stated objections to the “list of lists” approach in the

first place, and particular objections to lists that are non-scientific in nature and not generated or supported by authoritative bodies this is a particularly egregious provision.

Similarly, DTSC allows entire lists of chemicals to be added as Chemicals of Concern, but not the reverse. At a minimum, DTSC should allow petitions to *remove* entire lists as well.

#### **ARTICLE 5: ALTERNATIVES ASSESSMENTS**

While the Council is pleased that timelines in the current proposal are extended relative to previous versions it is still noted that the current proposed timelines of 12 months for a Final AA report submission as well as 60 days for DTSC to review and respond to the Final AA report are much too short to satisfy the comprehensive expectations of the information included in the report. By comparison submissions of request for authorization under the EU's REACH program allow 18-24 months to prepare and submit the report followed by 12 months for the European Chemicals Agency to respond and provide opinions. Given the amount of AA reports that will ultimately be submitted under the proposal it is reasonable to believe that the Department will quickly have a large back log and will have no opportunity to adequately review and respond within the 60 day time period. Given that a lack of response is stated to not signal acceptance this will quickly leave the regulated community at a loss to proceed with selected alternatives or with priority products for which no alternative was selected while awaiting feedback from DTSC.

#### **§69505.4: Alternative Assessments: Second Stage Subparagraph (A)(2)(C): Economic impacts – PAGE 43**

This provision requires the responsible entity to take into account all “projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered”. This is far too broad and complex an undertaking for almost any business, as most would be hard pressed to even provide estimates for all the factors involved. More importantly, there is insufficient agreement on the methodologies and scope to be used to deliver useful, reproducible results – and even those results will only be estimates.

#### **ARTICLE 6: REGULATORY RESPONSES**

#### **§ 69506.7(b): Engineered Safety Measures or Administrative Controls**

Under this provision, subparagraph (b) gives DTSC the authority to “integrally contain” a chemical of concern in a product. In other words, DTSC has the power to *redesign* a product and/or manufacturing process if it feels it is necessary to “enclose the hazard posed by the chemical of concern”. This is wholly

unacceptable. DTSC does not have the expertise to redesign personal care products, nor any of the thousands of other products in the marketplace.

Moreover, this subparagraph is completely unnecessary in light of the other regulatory responses that DTSC has provided itself, such as chemical restrictions and product prohibitions. As such, the Council requests that this subparagraph be delete in its entirety.

**§ 69506.11(b): Regulatory Duplication**

Assessing the scope of other laws that could potentially cover the product or chemical of concern, and whether they address the same concerns covered by the DTSC regulations, is the type of analysis that should be used in the initial stages of the regulatory process to determine whether the product or chemical should be regulated at all. Relegating this determination to the “regulatory response” stage of the process is inconsistent with the language prohibiting regulatory duplication and a waste of resources by DTSC and the regulated community.

To be sure, the Council supports the inclusion of a “regulatory duplication” provision that exempts consumer products already regulated by one or more federal or State of California regulatory programs, or international trade agreements, providing equivalent or greater protection of public health or the environment. For example, it is well understood that personal care products are comprehensively assessed for human health concerns and regulated by the U.S. Food and Drug Administration (FDA). Consequently, if a chemical-product combination is identified by DTSC *solely* because of questions on human health, and the product is a personal care product, there would be “regulatory duplication” with FDA and that product therefore would be exempt from these regulations.

Finally, the Council would also recommend amending the draft regulations to state that, where a federal or state agency has the *authority to regulate* (even if DTSC believes the extent to which this authority is exercised to be inadequate), this should be sufficient to justify an exemption. It is not for DTSC to judge if another agency is properly regulating a product, but only to understand if there exists regulatory duplication. If an exemption is provided for in these cases, and DTSC decides to regulate, it could potentially lead to overlapping regulations by different authorities, particularly if the other agency decides to regulate at some time in the future. This will result in confusion for the regulated community.

The Council strongly supports regulatory duplication to be considered early during the prioritization process and recognition that chemical-product combinations under consideration for human health

concerns in personal care products should be exempt from the AA process due to the fact that the products are already adequately regulated for human health by the FDA.

#### **ARTICLE 8: ACCREDITATION BODIES AND CERTIFIED ASSESSORS**

The entirety of Article 8 is unnecessary to the efficient implementation of the statute and should be eliminated.

DTSC justifies its decision to include this provision by stating in its Initial Statement of Reasons:

*By doing nothing or adopting the regulations without a certification process, DTSC would be required to conduct its outreach and training on AA through existing applicable and relevant mechanisms such as factsheets, mailers and workshops. Adoption of these regulations without including a certification process for assessors would:*

- *increase the amount of time required for DTSC's reviews of the work that is submitted;*
- *result in a lack of educational requirements and any person could prepare an AA;*
- *result in there being no mechanism to widely disseminate advancements in technologies and manufacturing practices; and*
- *result in a lack of consistency in quality and rigor in the preparation of AA.*

Unfortunately, this reasoning is flawed. First, DTSC is publishing an alternatives analysis guidance document following the promulgation of these regulations. There is no need for mailers and factsheets once the guidance is completed. Likewise, DTSC will be able to determine rather easily whether a responsible entity has complied with the process identified in the guidance, without the need for a certified assessor.

In addition, DTSC has a host of regulatory responses at its disposal to ensure that alternative analyses are properly conducted, and that responsible entities are sufficiently motivated to comply. There is no need for DTSC to add another layer of bureaucratic oversight to its green chemistry program.

Consider the problems raised by the proposed accreditation and certified assessor program. For example, how will it handle concerns with trade secret protection and confidential business information? There is no discussion of how trade secrets or confidential business information will be treated by certified assessors or accreditation bodies, which are not covered under Article 10 (which only applies to submissions to DTSC). Likewise, the criteria for becoming a certified assessor is so extensive that most people – even those with years of education and experience in conducting alternative analyses – would not qualify, severely hampering businesses hoping to use internal resources to meet this requirement.

Ms. Krysia Von Burg  
October 11, 2012  
Page **15** of **15**

For these and other reasons, the Council believes Article 8 should be deleted in its entirety. Otherwise, at a minimum, DTSC should clarify that the role of a certified assessor is merely to attest to conformance with the AA report format.

## **CONCLUSION**

While the proposed regulations may ultimately provide some benefit to public health and the environment, they also create regulatory inconsistencies and impose unnecessary costs upon industry. We appreciate that DTSC faces a statutory deadline for issuing these regulations, but we believe that it is critical that DTSC construct a program that is workable from the onset, with a narrowly drawn scope and requirements that are not cost-prohibitive.

To that end, the Council urges you to consider our comments to avoid creating barriers to innovation, detrimentally impacting the California and U.S. economy, and ultimately failing to improve protection of public health and the environment.

Sincerely,

Thomas F. Myers  
Associate General Counsel

**TATRO TEKOSKY SADWICK LLP**  
ATTORNEYS AT LAW

333 S. GRAND AVENUE, SUITE 4270  
LOS ANGELES, CALIFORNIA 90071  
TELEPHONE (213) 225-7171  
FACSIMILE (213) 225-7151

STEVEN R. TEKOSKY, ESQ  
(213) 225-7150  
STEVETEKOSKY@TTSMLAW.COM

October 11, 2012

*Via E-mail and U.S. Mail*

Ms. Krysia Von Burg, Regulations Coordinator  
California Department of Toxic Substances Control  
Regulations Section  
P.O. Box 806  
Sacramento, California 95812-0806

Re: Comments on Revised Text of the Regulations for  
Safer Consumer Product Alternatives

Dear Ms. Von Burg:

This letter submits Pharmavite LLC's comments on the latest text of the Proposed Regulations for Safer Consumer Product Alternatives. Pharmavite is one of the nation's leading dietary supplement manufacturers. As the latest version of the proposed regulations does not address, modify or resolve the issues, points and concerns raised by Pharmavite's previously-submitted comments regarding these regulations, Pharmavite submits the following comments to supplement, but not to supersede, Pharmavite's previously-submitted comments. Pharmavite requests that the current text be revised to address these comments and resolve Pharmavite's concern in a manner consistent with Pharmavite's position as expressed below.

The proposed regulations are intended to create a systematic, science-based approach to identify, evaluate, prioritize and regulate chemicals or chemical ingredients in consumer products. These are laudable goals and Pharmavite supports using a science-based approach for these complicated issues.

Pharmavite writes at the specific invitation of DTSC in connection with the scope of the exemption of “food” from the definition of “consumer product.” Pharmavite has reviewed the governing statutes, the draft regulations, the revised text of the draft regulations, DTSC’s explanatory information and documents, and comments submitted by the regulated community throughout this regulatory process. It generally appears in the proposed regulations’ explanatory documents and information, as well as from general DTSC commentary, that the regulations exempt food and do not seek to “capture” food within this regulatory program. This general intent to exempt notwithstanding, Pharmavite is concerned that these draft regulations may contain an overly narrow definition of the term “food” which creates a possible ambiguity about whether food ingredients are included within the food exemption. A clarification is needed to state expressly that the exemption for food includes both the finished food product and its individual ingredients. Pharmavite requests that the proposed regulations make clear that both food and food ingredients are exempt from the definition of “consumer product.”

Without the clarification Pharmavite seeks, there could be confusion as to whether the consumer product exemption is limited to food as a finished product and does not extend to food ingredients (components). For example, without the requested clarification, it might be asserted that orange juice intended to be incorporated as an ingredient in an orange flavored or juice-containing frozen food product would not be exempt while the same orange juice would be exempt if it were intended to be consumed as a beverage. The clarification Pharmavite seeks makes sense as under California as well as Federal law food ingredients (including dietary supplement ingredients) are defined as food.<sup>1</sup> We hope that these comments and suggestions provide an approach for resolving the potential and apparently inadvertent “capture” of food ingredients in the definition of “consumer product.” Accordingly, Pharmavite respectfully requests that draft § 69501(b) be revised to eliminate this potential confusion and to state explicitly that food as well as its ingredients are not consumer products for purposes of these regulations.<sup>2</sup>

---

<sup>1</sup> Pharmavite’s dietary supplement products, as well as their ingredients, are defined as food pursuant to both federal law (21 United States Code § 321(ff)) and state law (17 California Code of Regulations § 10200(b)). The federal program thoroughly and comprehensively regulates the safety of food and food components/ingredients. The FDA system is consistent with the purposes and goals of the proposed DTSC regulations, addressing the area fully and adequately. Adoption of the exemption for food components/ingredients avoids inconsistencies with applicable federal and California regulatory systems; it avoids a result that would be contrary to California Health & Safety Code § 25257.1(c); and it furthers the purpose of the state legislation.

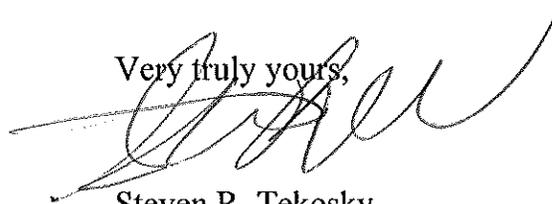
<sup>2</sup> Pharmavite does not want to duplicate the comments of others, and as there have already been substantial comments submitted on the issue of food packaging, Pharmavite merely wishes to state that it, too, believes that food packaging should be exempt from the definition of consumer product.

Ms. Krysia Von Burg  
October 11, 2012  
Page 3

**TATRO TEKOSKY SADWICK LLP**  
ATTORNEYS AT LAW

We appreciate the opportunity to assist your efforts to draft workable and appropriate science-based regulations and at the same time avoid a potential and apparently inadvertent “capture” of food ingredients in the definition of “consumer product.”

Very truly yours,

A handwritten signature in black ink, appearing to read 'S. Tekosky', written over a horizontal line.

Steven R. Tekosky

## GCREgs@DTSC

---

**From:** Yvonne Pierce <yvonnep373@comcast.net>  
**Sent:** Monday, October 01, 2012 5:43 PM  
**To:** GCREgs@DTSC  
**Subject:** State Chemical Disclosure Regulation

As a concerned grandmother, I urge the Department of Toxic Substances Control to resist lobbying efforts from the chemical industry and do what's right for future generations. I'm appalled that we have fallen behind Japan, Canada, and European nations in this regard.

Yvonne Pierce  
Corte Madera, CA



## Plastic Pipe and Fittings Association

800 Roosevelt Rd., Bldg. C, Suite 312 • Glen Ellyn, IL 60137-5833  
Phone: 630/858-6540 • Fax: 630/790-3095 • [www.ppfahome.org](http://www.ppfahome.org)

**Kryisia Von Burg,**  
**Regulations Coordinator Regulations**  
**Section Department of Toxic**  
**Substances (DTSC) Control P.O. Box 806**  
**Sacramento, CA 95812-0806**

[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Oct 11<sup>th</sup>, 2012

The Plastic Pipe and Fittings Association (PPFA) would like to thank the DTSC for the opportunity to comment on the California DTSC proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code.

PPFA is concerned that the complexity, scope and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to products that pose risks of harm and promoting innovation.

PPFA understands that many in the industry have input considerable effort to suggest meaningful, practical and legally defensible regulatory alternatives, and that the current proposal still demonstrates limited progress, and represents unscientific and over burdensome regulation.

Any state regulatory Green Chemistry program must contain a strong objective and scientific foundation in order to credibly inform choices made by consumers and other participants in the value chain. These foundations should not be material lists, but Life Cycle Analysis.

Although DTSC has estimated that some 1,200 substances will be covered by the regulation, the ACC estimates that the regulation would affect at least 4,000, if not more. This would strain both industry and the State of California.

PPFA is also concerned that the proposed SCP regulation will cause unwarranted concern and worry in the State's population, and potentially beyond to even include other States. How will citizens interpret that a thousand of the most commercially important substances are designated as subjects of the state's "concern," based only on a loose assessment of hazard characteristics gleaned from lists compiled by non-State entities?

In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer

products. More to the point, consumer apprehension will certainly lead to deselection – and for all the wrong reasons.

Because it identifies “chemicals of concern” and lacks a clear, scientific process for determining which chemicals and products would or could be selected for regulation, manufacturers and retailers would be left to guess at what would constitute a “safe” product or how to remain in compliance with the regulations. This kind of uncertainty is a massive disincentive to the development of better or safer products.

For example, if “safer” consumer products were to be chosen based on this method, using chemicals and material lists alone, this regulation could incorrectly recommend (and could force) the use of the worst in class products.

This materials list approach would seem to support the use of 100 year old Edison (incandescent) light bulbs. These Edison light bulbs seem to consist of only copper, aluminum and glass. It would seem this draft regulation would prefer the Edison bulb over all of the better (and likely future) lighting technologies – such as fluorescent, halogen, LED, and so on. This would pollute the environment, impact the air and water quality of California and waste more energy to satisfy an incorrect decision making regulation.

PPFA asks the DTSC to come back and propose a much simpler program based on LCA and abandon the incorrect pathway of materials and chemical lists for deselection of products.



October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Subject: Safer Consumer Product (SCP) Alternatives Proposed Regulation

Dear Ms. Von Burg:

SPI: The Plastics Industry Trade Association respectfully submits the following comments on California's Safer Consumer Product Alternatives proposed regulation, published on July 27, 2012.

SPI represents the third largest manufacturing industry in the United States, accounting for more than \$380 billion in annual shipments. In California, more than 2.4 million jobs are directly and indirectly tied to the plastics industry. The average wage of an industry employee is greater than \$41,000, excluding benefits. The industry's direct payroll including captive products is \$3 billion with dependent industries adding another \$94 billion to the state's payroll. Products of the plastics industry are utilized in almost every sector of the economy including agriculture, aerospace, automotive, electronics, medical, transportation, construction, packaging, recreation and sports and more.

We appreciate the considerable effort the Department of Toxic Substances Control (DTSC) has invested to develop the proposed rule and acknowledge the progress that has been made since the draft regulations were first released in 2010. Despite this effort, there remain outstanding issues for the regulated community that stakeholders have previously communicated to you throughout this process.

The regulations do not include a clear or science-based process by which the DTSC will select chemicals and products it regulates, resulting in great uncertainty for the regulated community. The proposal falls short in being science-based in a number of respects: identifying chemicals of concern through a merger of lists; and, in proposing a narrative, not a scientific standard and process for identifying priority products. Furthermore, we believe that the prioritization and evaluation process must be based on



October 11, 2012

SPI Comments to SCP Proposed Regulations

Page -2-

exposure and hazard. The wording of the proposal is such that the substitution of a compound not fully proven or subject to a rigorous safety evaluation runs the great risk of creating unintended consequences that could adversely impact the health of consumers, particularly the young, elderly and immuno-compromised, as well as the environment and the regulated community.

The proposal seeks to establish an all-encompassing program in which virtually all commercially available products and their packaging will be subject to the regulation and not simply common everyday consumer products. Full implementation of the rule as proposed would create a costly new government program requiring substantial resources. With competing budget priorities of the state, currently and going forward, the sustainability of this program remains highly questionable.

The regulations are written in a way that gives the department near-limitless discretion over a process that will be used to regulate consumer products. Compliance with the regulation will be a challenge for all entities as it appears to be an ever-shifting target. DTSC retains so much discretionary authority that it virtually eliminates any certainty that a business might have in terms of regulatory treatment.

The intent of the underlying statute, AB 1879 (Feuer-2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to promote the innovation of safer consumer products. However, the proposal continues to threaten businesses' intellectual property which is the basis for innovation.

The statute is clear on the matter of regulatory duplication, stating that it does not authorize the department to supersede the authority of other agencies and directing that the department shall not duplicate or adopt conflicting regulations for products already regulated or subject to pending regulation. The proposal goes beyond the statute. In referencing the Economic and Fiscal Impact Statement Form 399 accompanying the proposal, the state speaks narrowly to the regulatory authority of the U.S. Environmental Protection Agency, while remaining silent on the role and responsibility of the U.S. Food and Drug Administration (FDA) and the U.S. Occupational Safety and Health Administration (OSHA), among others. Yet the state proposes to duplicate those federal regulatory responsibilities under its proposal. For example, food contact materials are already fully regulated by the FDA. Further regulation of these materials by DTSC would be in direct conflict with the existing federal regulatory scheme. Including food contact materials within the scope of the proposal is duplicative, costly and may impede industry's development of new materials that can improve the safety, quality and availability of food products.

The requirement for an end-of-life program as called for in the proposal is excessive. Provisions are unnecessary, questionable and duplicative of responsibilities of other state agencies. The provisions

October 11, 2012  
SPI Comments to SCP Proposed Regulations  
Page -3-

cross jurisdictional boundaries and impose DTSC oversight on issues of solid waste management already under the authority of other state agencies, such as the Department of Resources Recycling and Recovery. These provisions expand DTSC's charter in an unnecessary manner, resulting in further costs to the state and regulated community.

Again, we recognize and appreciate the efforts put forth by the department, but we strongly encourage DTSC to continue to work with the regulated community of stakeholders to finalize a workable, practical and defensible proposal.

Should you have any questions or comments, you may contact me at: [jadams@plasticsindustry.org](mailto:jadams@plasticsindustry.org).

Sincerely,



Jane A. Adams  
Senior Director, State Government Affairs

cc:

The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business and Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



October 11, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Subject: TITLE 22, California Code of Regulations; 45-DAY PUBLIC NOTICE AND COMMENT PERIOD SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2011-02  
Office of Administrative Law Notice File Number: Z-2012-0717-04

E-mail Address: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Dear Ms. Von Burg:

On behalf of Plumbing Manufacturers International (PMI), we are submitting the following comments in response to the 45-day public notice and comment period for the California Safer Consumer Product Alternatives Act regulation.

PMI is the leading national and technical trade association of plumbing products manufacturers in the United States. Our 32 manufacturers and allied members include many of the well-known companies selling plumbing products in the United States for decades. Our collective group of manufacturers is responsible for at least 90% of all the fixtures and fittings sold in the U.S. market including California.

PMI is a strong advocate for the efficient and safe use of water, a commitment that is evident in our longstanding partnerships with the US Environmental Protection Agency's (EPA) WaterSense Program and with organizations such as the Alliance for Water Efficiency. We also advocate for public health and safety and product performance, as well as the harmonization of the requirements of plumbing codes and standards.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort the Department of Toxic Substances Control [DTSC] has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more

focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft. We remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

One of the most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on **exposure** and **hazard**, and it must avoid duplication and conflicting regulatory requirements.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as its starting point. Upon removal of statutorily exempt chemicals and duplicates, the department predicts a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports this two step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying its list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

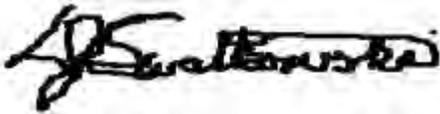
The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer

products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

In conclusion, PMI feels it is important that the process be revised to one that is workable and achievable with regard to the scope, the prioritization of products, the prioritization of chemicals, the alternative analysis, and the reporting requirements. We would urge the DTSC to fully endorse and adopt PMI's comments and requests for guidance for the Safer Consumer Product Alternatives Act regulation and move to ensure the logical, efficient and transparent implementation of the Act.

Sincerely,



**Len Swatkowski**

Technical Director

Plumbing Manufacturers International

1921-G Rohlwing Road

Rolling Meadows, IL 60008

p: 847.481.5500 x 105

f: 847.481.5501

c: 614.406.2352

cc: The Honorable Matt Rodriguez, Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Miriam Ingenito, Deputy Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Kristin Stauffacher, Assistant Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Nancy McFadden, Cabinet Secretary, Office of the Governor [nancy.mcfadden@gov.ca.gov](mailto:nancy.mcfadden@gov.ca.gov)

Mike Rossi, Senior Business & Economic Advisor, Office of the Governor [mike.rossi@gov.ca.gov](mailto:mike.rossi@gov.ca.gov)

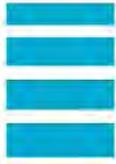
Cliff Rechtschaffen, Senior Advisor, Office of the Governor [cliff.rechtschaffen@gov.ca.gov](mailto:cliff.rechtschaffen@gov.ca.gov)

Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor [martha.guzman-aceves@gov.ca.gov](mailto:martha.guzman-aceves@gov.ca.gov)

Barbara C Higgins, Executive Director, PMI

Jerry Desmond Jr., Desmond & Desmond. PMI Legislative Advocate

American Standard Brands, Inc. \* Amerikam, Inc. \* Bradley Corporation \* BrassCraft Mfg. Co. \* Chase Brass & Copper Company \* CSA International \* Delta Faucet Company \* Dornbracht Americas \* Duravit USA \* Elkay Manufacturing Company \* Fisher Manufacturing Company \* Fluidmaster, Inc. \* Gerber/Danze Plumbing Fixtures LLC \* Hansgrohe, Inc. \* IAPMO \* InSinkErator \* Kohler Company \* KWC America, Inc. \* Lavelle Industries \* LSP Products \* Moen Incorporated \* Mueller Brass Company \* NEOPERL, Inc. \* Pfister \* Sloan Valve Company \* Speakman Company \* Symmons Industries Inc. \* T & S Brass and Bronze Works, Inc. \* TOTO USA \* VitrA USA \* Water Pik \* WCM Industries, Inc.



## Camie-Campbell, Inc.

9225 Watson Industrial Park St. Louis, MO 63126  
800-325-9572 314-968-3222 FAX: 314-968-0741 [www.camie.com](http://www.camie.com)

September 14, 2012

Krysia Von Burg, Regulations Coordinator  
Regulations Section Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

### **Re: PLZ Aerospace Corporation Comments on Safer Consumer Products Draft Regulation (July 2012)**

Dear Ms.Von Burg:

On behalf of PLZ Aerospace, I respectfully submit the following comments regarding the Department of Toxic Substances Control's draft Safer Consumer Products Regulation dated July 27<sup>th</sup>, 2012.

PLZ Corporation has acquired seven specialty chemical companies that all have been in the industry for many years. They are Claire Products, Sprayway, CPC, Camie, K-G Spray Pak and Assured Packaging. Our product lines service the I&I market, Industrial and some retail. We manufacture aerosol adhesives, lubricants, cleaners, air fresheners, automotive products and other specialty products. We have manufacturing facilities in Missouri and in Canada and employ over 500 people.

I appreciate the opportunity to provide comments on such an important issue. I would like to start by noting that my company appreciates the reduced number of chemicals that will make up the initial Chemical of Concern list. This is more realistic and will make it easier for industry to determine the impact of the green chemistry program on products sold in California. I would also like to thank the department for the process it has used to allow for extensive input from all stakeholders.

My company, however, continues to have concerns with many aspects of the regulations and the impact the program will have on our company and products. Although PLZ has a large work force, our R&D staff is small and seems to spend most of its time formulating for regulatory compliance. The margins in this industry do not allow us to increase our R&D budget. One of our largest concerns is being able to respond to the increase in workload related to this regulation. We appreciate the fact that you will address only 5 Priority products at a time, however, this may equate to



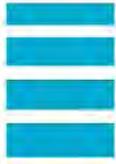
California VOC Compliant Products



Chemical Specialty Products



Earth-Friendly Biodegradable Products



## Camie-Campbell, Inc.

9225 Watson Industrial Park St. Louis, MO 63126  
800-325-9572 314-968-3222 FAX: 314-968-0741 [www.camie.com](http://www.camie.com)

many formulas for each product for us. We still feel that this may be more than industry can handle, depending on the complexity of the formulas.

The deadlines that are included in the regulation will also be a major concern for us. We feel that we will need more than 60 days for Priority Product Notification and more time for the preliminary and final Alternative Analysis Report. This is especially true for our adhesive and coatings formulas which have many formulation limitations due to compatibility and performance requirements.

Another issue that is especially troubling for our adhesive products in particular is the issue of trade secret formulas. The solids composition of our products is proprietary and is what allows us to maintain market share. If that information is made public it will allow our competitors to easily duplicate our products.

Specialty chemical products improve the quality of life for most Californians. Our product offerings allow consumers to maintain and improve their possessions. The PLZ Corporation is proud to conduct business in the state of California, but it must be noted that it is becoming increasingly difficult to do so. If this regulation were approved as currently drafted, the company will be faced with uncertainty, fiscal hurdles and less opportunity for innovation. PLZ hopes that providing these comments will help advance efforts to create a practical, scientifically-based, and legally defensible regulation.

Respectfully,

Jim McLarty  
Director of Regulatory Affairs  
PLZ Aerospace Corporation  
1000 Integram Drive  
Pacific, MO 63069

Ph: 636-334-9100  
[jmclarty@plzaeroscience.com](mailto:jmclarty@plzaeroscience.com)



California VOC Compliant Products



Chemical Specialty Products



Earth-Friendly Biodegradable Products



**The Procter & Gamble Company**

NA Regulatory & Technical Relations  
One Procter & Gamble Plaza (C-6)  
Cincinnati, OH 45202  
www.pg.com

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 27, 2012)**

Dear Ms. Von Burg:

The Procter & Gamble Company (P&G)<sup>1</sup> appreciates this opportunity to comment on the proposed Safer Consumer Product Alternatives Regulation<sup>2</sup> (“proposed regulation”) released on July 27, 2012, by the California Department of Toxic Substances Control (“DTSC” or “Department”) for the implementation of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008).

**General Comments**

P&G continues to fully support what we believe was the original vision for California’s inception and development of the Green Chemistry Initiative; that is, to create the opportunity and incentives to accelerate and promote sustainable innovation while making meaningful improvements in the protection of the environment and health of California consumers and their children. We recognize the considerable effort DTSC has once again invested in this latest effort to develop an effective regulatory system to implement the Green Chemistry Initiative in the state.

Director Raphael has often described her vision for creating a regulatory program to implement the Green Chemistry Initiative that is “practical, meaningful and legally defensible.” We see evidence of this vision in the Department’s decision to initially focus implementation of the program on an identified small collection of (up to five) Priority Products. This is a practical approach that will enable the Department to pilot this unique

---

<sup>1</sup> The Procter & Gamble Company is the world’s leading consumer products company operating in more than 80 countries worldwide. Our strong portfolio of recognized, quality and leadership brands includes numerous household, industrial and personal care products. Procter & Gamble is fully committed to helping solve sustainability challenges, which is embedded in our Company Purpose “to improve the lives of the world’s consumers, now and for generations to come.” Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

<sup>2</sup> <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsNoUnderlineJuly2012.pdf>

program, to learn over time and to make adjustments according to what works and what does not work. The practicality of this promising start unfortunately becomes lost with the ensuing, complex regulatory scheme that far exceeds that which is needed in the conduct of an initial phase and generates paperwork and program administration duties far in excess of what DTSC resources can support.

### **Primary Concern**

The clear persuasion in the proposed regulation for substitution with a “safer” alternative as an outcome of the Alternatives Assessment (AA) process fails to appropriately recognize and implement the more holistic, risk-based approach outlined in AB 1879. The statute requires an evaluation of potential hazards and critical exposure pathways to determine the right course of action to reduce risk. One possible action identified in the statute is “no action,” which is an indication that DTSC must consider the overall safety of a Priority Product – with no change – as an equally potential outcome as substitution with an alternative. Unfortunately, DTSC has distanced the Safer Consumer Product Alternatives Regulation from the clear direction provided in AB 1879 and has developed a proposed regulation that favors replacement of Chemicals of Concern with less hazardous alternatives (to the maximum extent feasible) over a more holistic, risk-based approach. P&G strongly asserts that a risk-based evaluation of Chemicals of Concern in Priority Products is the solution that will deliver meaningful and measurable improvements in public health and environmental protection. DTSC’s continued focus on minimizing hazard will miss the opportunity for game-changing, sustainable innovations that deliver significant environmental benefits and realize the original vision of the Green Chemistry Initiative for California.

P&G has expended significant resources over the last five years sharing our scientific expertise in consumer product safety and alternatives analysis with DTSC -- from the genesis of the Green Chemistry Initiative, through the legislative enrollment of AB 1879 and SB 509 and the numerous informal draft regulations, by George Daston’s participation on the Green Ribbon Science Panel and lectures by our top scientists at DTSC symposia, to engagement in the current formal rulemaking process. Throughout this entire journey, we’ve demonstrated the significant attention to product safety that we, and other leading industry partners, apply to our trusted brands. Green Chemistry thinking has shaped our ingredient choices from the very start of the product design process for decades. At P&G, we were evaluating life cycle impacts of our products to identify opportunity areas long before “life cycle analysis” became a recognized practice in the industry. We’ve freely shared with DTSC our science, expertise and learnings collected through trial, error and discovery to help shape the implementation of the Green Chemistry Initiative. Our commitment to this effort grew from a core belief that, if implemented correctly, this program would firmly position California (and the United States) as a global leader of sustainable innovation and evolved chemical management.

We believe that a very different outcome will emerge from implementation of the current proposed regulation than the optimistic vision from which this journey began. Instead of California leading the world as the entrepreneurial birthplace of sustainable innovation, the state will likely trail other geographies in the competitive global marketplace due to the slow emergence of technology that can successfully navigate the

complex regulatory environment. Further, the economic impact this regulation will have on California businesses and manufacturers who sell to California consumers is uncertain because of its broad scope and untested provisions; however, an independent analysis by the California Foundation for Commerce and Education (CFCE) predicts total net costs to California businesses and consumers to approach \$150 billion in the first 25 years of implementation.<sup>3</sup> These dire predictions for California during this period of slow economic recovery sharply contrast with the original promise of the California Green Chemistry Initiative and leave the regulated community questioning the purpose and effectiveness of the command-and-control regulatory proposal before us now.

### **Recommendation**

P&G is a member of, and active participant in, the Green Chemistry Alliance (GCA), a group of major trade associations and companies that represent numerous broad industrial sectors in California. We support the written comments of the Green Chemistry Alliance, as well as those of our individual Industry trade associations, including the American Chemistry Council (ACC), the American Cleaning Institute (ACI), the Consumer Specialty Products Association (CSPA), the Grocery Manufacturers Association (GMA) and the Personal Care Products Council (PCPC). We join the voices of these organizations and the numerous member companies that comprise them in our recommendation to DTSC to revise the direction of the proposed regulation to fully achieve Director Raphael's vision of a "practical, meaningful and legally defensible" program. We strongly recommend that DTSC consider the following points to guide further refinement of the regulation:

- Implement a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on a risk-based evaluation of hazard, exposure and the likelihood of harm. This approach will deliver the **meaningful** results of Director Raphael's vision by achieving measureable improvements in public health and environmental benefit. The risk-based approach will focus DTSC's limited resources on opportunity areas and yield the best overall outcome for California in terms of meaningful results and economic impact.
- Develop appropriate criteria to identify Chemicals of Concern and a risk-based process that evaluates both exposure and hazard to prioritize Chemicals of Concern and the Priority Products in which they are present. This is a critically important improvement needed in the regulation to address the statutory requirement for such a process and to improve transparency of the program for the regulated community and interested stakeholders. DTSC's attention to this starting point of the program is necessary to strengthen and align the proposed regulation with a second component of Director Raphael's vision, which is to ensure the Safer Consumer Product Alternatives Regulation is **legally defensible**. Furthermore, the proposed regulation threatens vital intellectual property upon which US innovation is based, requiring submission of information that is unnecessary and far in excess of the substantiation required for protection of confidential business information under the

---

<sup>3</sup> <http://www.calchamber.com/Headlines/Pages/10082012-NewConsumerProductRulesFailtheTestofGoodEconomics.aspx>

California Uniform Trade Secrets Act “UTSA” (Civil Code sections 3426.1-3426.11). The broad discretion afforded to the Department in the proposed regulation to make a decision about a trade secret claim is inconsistent with California state law. This inconsistency again raises a question of the legal defensibility of the proposed regulation. The importance of trade secret protection to a functioning, competitive marketplace cannot be overstated. We implore DTSC to tighten the trade secret provisions of Article 10 (consistent with UTSA) and preserve a competitive environment in which sustainable innovation fuels the California economy.

- Simplify and focus the regulation to address the third component of Director Raphael’s vision. The overly broad scope and complexity of the proposed regulation raises numerous *practical* problems. For example, a starting collection of approximately 4,000 discrete Chemicals of Concern comprised by the identified 22 lists of hazardous chemical substances and chemical classes, and the lack of a clear prioritization process for Chemicals of Concern in Priority Products, provide no guidance to the regulated community as to where to anticipate regulatory compliance effort. An unknown *de minimis* threshold for all possible presence of a Chemical of Concern in a Priority Product (including intentional addition as an ingredient and mere presence at trace levels as a contaminant) provides no upfront regulatory certainty if a manufacturer or their recognized brand is within scope of the reporting, alternative analysis and supply chain communication obligations discussed in the proposed regulation. This uncertainty facing the regulated community; the sheer workload awaiting DTSC staff when the regulatory submissions begin; and the expected economic impacts that will reverberate throughout industry as a result of compliance activities and loss of trade secret information collectively scream that this proposed regulation is far from practical.

We respectfully submit the attached, detailed comments to address the provisions of the proposed regulation that require attention prior to issuance of a final rule. These provisions are critical to establish a practical, meaningful and legally defensible regulatory framework and have been developed through the collective expertise of our industry trade associations and the membership of the Green Chemistry Alliance.

P&G remains committed to working collaboratively with DTSC, industry partners and other key stakeholders to develop a workable regulatory framework to achieve the promise and vision of the Green Chemistry Initiative. We agree with Director Raphael that an emphasis on practicality, legal defensibility and successful achievement of meaningful and measureable improvements in public health and environmental protection is undoubtedly the right goal and mission for this rulemaking process. We strongly encourage DTSC to carefully review and consider the comments and recommendations presented by the regulated community to make the right decisions in this rulemaking process for California’s consumers, the state’s natural environment, the state’s economy and the future of sustainable innovation in the United States. The proposed Safer Consumer Product Alternatives Regulation will be the landmark framework against which other U.S. states and geographies model; we entreat the Department to undertake this responsibility thoughtfully and with full

consideration of the expected economic impact and implications for innovation flexibility of the consumer product industry.

Should you have any questions about these comments, please contact me directly at (513) 983-2531 or [froelicher.jm@pg.com](mailto:froelicher.jm@pg.com) or contact Beth Percynski in P&G's Sacramento office at (916) 442-3135 or [percynski.ba@pg.com](mailto:percynski.ba@pg.com).

Sincerely,

Julie Froelicher  
NA Regulatory & Technical Relations Manager  
The Procter & Gamble Company  
One Procter & Gamble Plaza  
Cincinnati, OH 45202  
(513) 983-2531  
[froelicher.jm@pg.com](mailto:froelicher.jm@pg.com)

cc: The Honorable Matt Rodriguez, Secretary, CalEPA, [MRodriguez@Calepa.ca.gov](mailto:MRodriguez@Calepa.ca.gov)  
Miriam Ingenito, Deputy Secretary, CalEPA, [mingenito@calepa.ca.gov](mailto:mingenito@calepa.ca.gov)  
Kristin Stauffacher, Assistant Secretary, CalEPA, [kstauffacher@calepa.ca.gov](mailto:kstauffacher@calepa.ca.gov)  
Nancy McFadden, Cabinet Secretary, Office of the Governor, [Nancy.McFadden@gov.ca.gov](mailto:Nancy.McFadden@gov.ca.gov)  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor, [Mike.Rossi@gov.ca.gov](mailto:Mike.Rossi@gov.ca.gov)  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor, [Cliff.Rechtschaffen@gov.ca.gov](mailto:Cliff.Rechtschaffen@gov.ca.gov)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor, [martha.guzman-aceves@gov.ca.gov](mailto:martha.guzman-aceves@gov.ca.gov)

## Detailed Comments on the Proposed Safer Consumer Product Alternatives Regulation The Procter & Gamble Company

### Overarching Issues

**Regulatory Duplication.** It is essential that the proposed regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently reviewed in the US. The foundational question upon which identification and prioritization of Chemicals of Concern/Priority Products must commence is whether another agency already regulates the potential health or environmental impact from the Chemical of Concern in the subject product. An affirmative answer to this question prohibits the Department from any further action because of regulatory duplication, which is prohibited by the statute. For example, it is well understood that personal care products are comprehensively assessed for human health concerns and regulated by the U.S. Food and Drug Administration (FDA). Consequently, if a chemical-product combination is identified by DTSC *solely* because of questions on human health, and the product is a personal care product, there would be “regulatory duplication” with FDA and that product would be exempt from the regulation.

The proposed regulation gives the Department the discretion to determine the adequacy of the regulatory requirements currently in place as they compare to the breadth of the Safer Consumer Product Alternatives Regulation’s governance. The Legislature did not intend this discretion, as evidenced by the language of SB 509 (Simitian, 2008). This is an example of regulatory overreach by suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. The Department has no authority to pass judgment on the sufficiency of current regulatory authority and implementation. The statute under SB 509 (Simitian, 2008; Health & Safety Code §25257.1(b) and (c)) is clear on the matter, with two applicable provisions:

*(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.*

*(c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.*

The proposed regulation goes beyond the statute by asserting the Department’s authority to provide a level of public health and environmental protection for a Priority Product that is equivalent to or greater than the protection provided by other agencies under other regulatory constructs.

Furthermore, there are limited, if any, benefits from the proposed regulation considering the current federal oversight of consumer product safety. The U.S. Environmental Protection Agency (EPA) administers the Toxic Substances Control Act (TSCA) to regulate chemical ingredients in consumer products and prevent those substances that present an unreasonable risk of injury or illness to human health or the environment from commercialization in the U.S. The Consumer Product Safety Commission (CPSC) administers the Federal

Hazardous Substances Act (FHSA) and other statutes that protect the public from unreasonable risk of injury or illness during the use of consumer products. Likewise, federal law prohibits the marketing of adulterated cosmetics that contain any poisonous or deleterious substance that may render them injurious under the Federal Food, Drug and Cosmetics Act. In addition to these national, uniform standards, consumer product manufacturers already have strong product stewardship programs and market incentives to ensure that their products are safe and effective. The proposed regulation seeks to replace these existing protections with local government mandates and disrupt the natural order of a free market economy by authorizing DTSC to supplant the purchasing choice of California consumers and dictate whether or not products – *including safe products* – can be marketed in California.

Finally, P&G fully supports the request made by the Personal Care Products Council in their written comments to remove Over-The-Counter (OTC) drugs from the scope of the regulation. DTSC regulation of OTC drugs is unnecessary because of the extensive existing oversight by the Federal Food and Drug Administration (FDA) with respect to OTC drug labeling and product ingredients. For example, topical OTCs must either conform strictly to monograph provisions regarding active content and labeling, or they must be approved individually through FDA's pre-market drug approval process. Any attempt by DTSC to implement a regulatory response that would run counter to the FDA mandates for either labeling or ingredients would face a significant pre-emption risk. The proposed regulation exempts prescription drugs and medical devices for precisely the same reasons that DTSC should exempt OTC drugs from the scope of this regulation.

**Science-based Processes.** To build confidence in the Green Chemistry Program, DTSC needs to operate the program with a rigorous, science-based approach, in concert with state, federal and international best practices. DTSC needs to consistently apply such an approach to implementation of the entire regulation, beginning with the selection Chemicals of Concern and Priority Products, to the identification of an AA Threshold, throughout the AA process and in the determination of appropriate and proportionate regulatory responses. The proposed regulation raises significant concerns that the Department does not intend to consistently apply an objective, science-based process, but instead structure and administer a program that responds to the latest sensationalist media story or activist agenda. The concerns start with the use of the narrative standard, which is ultimately subjective and facilitates a political, not scientific, basis for prioritization. Inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure" provide additional reason for concern since neither definition requires a means to assess the quality of information. Concerns are further exacerbated with an absence of emphasis on a weight-of-evidence evaluation of information. Instead, dependence rests upon the "most protective" study independent of its actual quality and reliability. Indication that decisions should be driven by the "greater amount of information" rather than conclusions from the most relevant and highest quality studies further alarm the reader that an objective, science-based process is absent from the proposed regulation.

We strongly assert that DTSC's evaluation of information to make decisions and substantiate conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts" need to be guided by the following principles:

- The decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for stakeholders to have sufficient confidence in the Department’s health and environmental regulatory decision-making.
- All evaluations must rely on the best available scientific information regarding possible hazards and risks of substances, and employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure.
- DTSC must establish upfront, transparent criteria and then consistently apply the criteria throughout the evaluation process to identify studies and to evaluate their quality, relevance, and reliability.
- DTSC must base all evaluations on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.
- DTSC must objectively characterize and present hazards and risks in a manner understandable to stakeholders and risk managers and provide a full picture of what is known and what has been inferred.
- Assessments must provide full disclosure of key information. When DTSC uses assumptions (or policy preferences) in lieu of scientific data, DTSC must disclose the assumptions (and policy preferences) along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

DTSC should incorporate these principles into Article 1 of the regulation to provide the overall theme and foundation for science-based implementation.

### Specific Issues

#### **Article 1 - §69501 General**

**§69501.1 – Definitions.** Definitions for “**adverse impacts**”, “**reliable information**” and “**reliable information demonstrating the occurrence of exposures**” remain scientifically inadequate. They focus on the existence of a hazard or exposure only. No thresholds are included to account for potency and likelihood of harm in making decisions and implementing the regulation.

**(19) Chemical** – A chemical ingredient is one that is intentionally added to serve a function in the final product and should be the focus of this regulation for the reasons discussed throughout these comments. The following revision is suggested:

“Chemical” means [19(A)(1)...] ~~or~~ **and intentionally added above the Alternative Analysis threshold to serve an intended function** in a consumer product.

The “molecular identity” definition appears in 19(B) to clarify use of this term in the description of “chemical” in 19(A)(1). The definition of “molecular identity” has been expanded to include consideration of physical properties of ingredient. This seems appropriate since these properties are routinely considered in the safety assessment of products and their ingredients. The relevance of these physical properties will depend on the application and use of the ingredient and not all will be relevant for a determination of safety. This decision can only be made as part of a risk assessment process by an assessor knowledgeable about how the ingredient is used. We applaud the DTSC for recognizing this need for expert judgment in the proposed regulation and encourage you to maintain your commitment to this in the final application of this regulation.

**(22) Consumer Product** – The consumer product definition in the proposed regulation revokes the bulk chemical exemption that appeared in the October 2011 informal draft as §69501(b)(2). This change is inconsistent with the focus of the Safer Consumer Product Alternatives Regulation to find functionally acceptable and technologically and commercially feasible alternatives for Chemical(s) of Concern in Priority Products widely used in consumer homes throughout the state. The California Division of Occupational Safety and Health (Cal/OSHA) protects workers from safety hazards and unreasonable exposures in the occupational environment within the state. Similarly, the Occupational Safety and Health Administration (OSHA) enforces workplace safety and health at the federal level. The Department of Transportation (DOT) and Department of Homeland Security (DHS) regulate the movement and transport of bulk chemicals, so a regulatory infrastructure already exists at the federal and state level to protect (and manage any improvements) in the health and safety of California’s workforce. The inclusion of bulk chemicals within the scope of the proposed regulation presents a case of regulatory duplication.

**(31) Functionally acceptable** - The regulation proposes a change from the earlier draft definition, which stated that the alternative “substantially equals or exceeds the performance and functionality of the original product.” The proposed definition appropriately recognizes the importance of consumer acceptance of an alternative in the overall evaluation of “acceptable” (i.e., “the product performs the functions of the original product sufficiently well that a consumer can reasonably be anticipated to accept the product in the marketplace”). Recognition is needed that consumer acceptance is not directly and quickly measurable and may add many months to the AA timeline to enable sufficient consumer testing to draw a conclusion.

**(34) Homogeneous Material** – DTSC has eliminated the earlier recognition of “assembled product” and replaced with the new term, “homogeneous material,” in this proposal. A homogenous material could potentially become the focus of an AA by being defined as a “product” which means, among other things

"A component, or a homogeneous material within a component, that is identified, under section 69503.4(a)(2)(B), as the minimum required focus of an AA."

While six substances are restricted at the homogenous material level in electronic products in European Union's Restriction of Hazardous Substances (RoHS) Directive, this concept is not appropriate for the scope of chemicals and products that will be covered in the California regulation. There would be great difficulty and uncertainty in defining it and in the case of polymers there would be an infinite number of variations. Beyond the impracticality, it's not clear why this is needed – "component" should satisfy all needs for the focus of an AA. For the following reasons, we recommend removal of this term and that the regulation focus on "component" in addressing assembled article types of products.

- Very difficult to enforce compared to a focus on the component level. A company cannot easily test to this definition, creating ambiguity for both the agency and regulated community
- Currently this is a specific regulatory term for a single sector (electronic industry) and applies only to a small number of regulated substances – not broadly applicable nor scalable to other consumer product sectors
- Information on assembled products is being collected in supply chains at the level of component / article for substances of very high concern under REACH. The homogeneous materials concept brings into question whether these data would be applicable for California, resulting in longer implementation timelines and significant additional administrative burden for agency/industry with minimal environmental benefit.

**(38) Legal requirements** - Regulations in other states or countries are not acknowledged in the proposed regulation. For instance, many products are made for the North American or even global market. The following revisions are suggested:

"Legal requirements" means specifications and/or performance standards that a chemical, ~~or~~ a product, ~~or~~ product packaging **or labeling** is required to meet by federal, California **or other state or international** law.

**(52) Reliable Information** – While there are some helpful improvements to this definition, DTSC has yet to address or resolve the fundamental problem. The revised definition identifies a wide variety of sources of scientific information and makes a *de facto* determination that they are "reliable." All of the sources mentioned are appropriate for consideration in making decisions. Some include deliberative scientific processes that actually review the information in studies and judge weight-of-evidence and other factors (e.g., National Academies and reports from government agencies). In such cases, they may be considered reliable. However, defining "reliable" information from sources not widely recognized in the scientific community as "authoritative bodies" unnecessarily introduces question, and potential controversy, into a program that is intended to be science-based. For example, the reference in (A) is problematic: "Published in a scientifically

peer reviewed report or other literature.” “Other literature” is open-ended and could include all manner of unreliable information.

What would DTSC do in a case where there are four peer-reviewed studies that provide entirely different results, or four studies from a variety of the listed sources that come to different conclusions? By the Department’s current definition they are all “reliable information.”

The need for a mechanism to judge studies for relevance and reliability is widely recognized by federal agencies with health and safety responsibility and in international forums. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology has been used for determining data quality and reliability on tens of thousands of studies for over 2,000 chemicals in U.S. and OECD High Production Volume (HPV) programs. The hundreds of thousands of studies on over 5,000 chemicals that industry has submitted under REACH were rated according to this approach. The methodology is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies<sup>4</sup>.

We reiterate the recommendation that industry has presented to DTSC in earlier, informal draft versions of the proposed rule to provide separate definitions for “Information Sources” to include the diverse sources listed in (52) and (53) and then to determine reliability by subjecting those studies to this definition for “Reliable Information” based on the OECD Manual:

*“Reliable information” is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship (“QSAR”) approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies. [http://www.oecd.org/document/7/0,2340,en\\_2649\\_34379\\_1947463\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html)*

**(54) Responsible entity** – The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the Federal Trade Commission’s (FTC) Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (California Air Resources Board-ARB, CPSC, etc.). All consumer commodities that are legally distributed in U.S. commerce must comply with the Federal Trade Commission labeling requirements, so identification of the responsible entity is simple. As such, subsections (B) and (C) should be eliminated.

---

<sup>4</sup> [http://www.oecd.org/document/7/0,2340,en\\_2649\\_34379\\_1947463\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html).

**(56) Safer alternative** – Recommend a change in the definition: “Safer alternative” means a **functionally acceptable** alternative that, in comparison with the existing Priority Product, ~~reduces, avoids, or eliminates the use of, and/or potential exposures to, one or more Chemical(s) of Concern, so as is determined by the~~ **Alternatives Analysis** to reduce adverse public health and environmental impacts.

**(58) Sensitive subpopulations** - The definition of “sensitive subpopulation” refers to “individuals with a history of illness” and “workers.” The reference to “a history of illness” is exceedingly broad and somewhat ambiguous as to what constitutes “illness.” We recommend deleting this reference to individuals with a history of illness (or modifying the term to conform to DTSC’s intent to cover only those “serious” or “chronic” illnesses affecting a meaningful portion of the population). DTSC should also delete all references to workers (whose health is regulated by Cal/OSHA) before finalizing the regulation.

**Adverse Impacts** – Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, and waste/end-of-life related to hazard traits. Many traits are traditional endpoints addressed in state, federal and international chemical programs. However, there are several critical concerns in these definitions.

**Reliance on Emerging Science** –The first is that some factors recognize scientific frontier issues—for instance epigenetic toxicity—that are not settled science and lack widely accepted evaluation methodologies. These factors appear in the proposed regulation because they are included in OEHHA’s hazard traits. We fully support ACI’s written comments on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), which are currently available on the OEHHA website.<sup>5,6</sup> As discussed in ACI’s comments, the OEHHA hazard trait regulation includes many elements that are unauthorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. As such, DTSC’s proposed regulation should not reference Chapter 54.

**Thresholds** – An overriding concern with the adverse impact and chemical property definitions is that there are no threshold levels to provide a context for what is of concern. The absence of thresholds in the proposed regulation suggests that every substance could be considered a Chemical of Concern or be included for the purposes of AA Threshold determination, Alternative Analysis and regulatory response because it has some impact, regardless of potency. Thresholds are a part of chemical control systems worldwide as a means to help identify priorities. The definitions should include thresholds and clearly convey the potential for adverse impacts in the context of thresholds.

**Bioaccumulation** – Industry stakeholders have previously noted that the proposed definition for bioaccumulation is inconsistent with nationally and internationally accepted definitions, which specifically include thresholds. Peer reviewers have also commented on this issue. In this iteration,

---

<sup>5</sup> <http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf>

<sup>6</sup> <http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf>

there is further confusion by reference to both the previous DTSC definition AND a reference to OEHHA's hazard traits. It's not clear why such an important chemical property, with a long history of federal and international standard setting and chemical control actions, should be defined uniquely in California. We join our industry partners in reiterating the recommendation that DTSC change the bioaccumulation definition consistent with the Society of Environmental Toxicology and Chemistry's (SETAC) Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of bioaccumulation science.<sup>7,8</sup>

**§69501.2 – Duty to Comply and Consequences of Non-Compliance.** In Section 69501.2(a), the requirements for compliance should be limited to the manufacturer of the product or responsible entity as identified on the product label, per the requirements of FPLA. The manufacturer has the knowledge of the formulary science that produced the Priority Product and is the most knowledgeable entity in the supply chain to manage the AA requirements, including the potential selection of a functionally acceptable alternative that is compatible with the product formulation. As such, references to the importer or retailer should be eliminated.

**§69501.4 – Chemical and Product Information.** Under subsection (a)(4), the Department would give itself unlimited authority to require a manufacturer or importer to generate and obtain information with no accountability. There should be boundaries regarding the kind of information that the Department may seek, and due process for those to whom the Department is making the request.

**§ 69501.5 – Availability of Information on the Department's Website.** The Department should use official state regulatory dissemination methods (e.g., California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the Safer Consumer Product Alternatives Regulation.

## **Article 2 - §69502 Chemicals of Concern Identification Process**

The proposed regulation starts with a consolidated list of chemicals from 22 source lists at the effective date of the Regulation, resulting from the merging of all the items on the lists. These lists contain well over 4,000 distinct chemicals. Though DTSC has indicated that the published list will contain 1,200 chemicals, the Department has not indicated how the reduction will take place other than to take out the approximately 450 pesticides and pharmaceuticals that are exempted from the regulation.<sup>9</sup> There are several major concerns with this approach, as follows:

---

<sup>7</sup> Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.

<sup>8</sup> <http://www.setac.org/sites/default/files/ExecutiveSummary.pdf>

<sup>9</sup> This regulation, like every other chemical regulation, must specify unique Chemical Abstract Services numbers (CAS RN) and cannot utilize generic chemical categories. For instance, the perfluoro chemical category contains many hundreds of different unique CAS RN chemicals. Responsive compliance and the enforceability of the regulations requires the clarity of a unique CAS RN associated with Chemical of Concern lists and carried through each subsequent element of the regulation.

- The statute requires that DTSC establish a process to prioritize Chemicals of Concern. The proposed regulation does not articulate a prioritization process whatsoever, and therefore, does not deliver the statutory mandate.
- While listing 4,000 or 1,200 chemicals may give the appearance of providing expansive public protection, the action creates a meaningless and untargeted concoction. Nearly 50% of the over 4,000 substances are not even listed on the TSCA Inventory, making them illegal in US commerce<sup>10</sup>. More than 80% were not reported as manufactured or imported into the US in EPA's most recent Chemical Data Reporting (CDR) Rule update; and 90% are not used in consumer products.
- The establishment of a non-credible list of 4,000 or even 1,200 substances will become irrelevant and do little to motivate broad-based, proactive action by manufacturers. The overwhelming number of chemicals on this list likely drive manufacturers to focus resources only on those identified as Chemicals of Concern in selected Priority Products.
- It is much more appropriate to refer to this larger list as "Chemicals of Interest" (or similar), and for DTSC to establish a narrowed list of "Chemicals of Concern."

Actual prioritization of Chemicals of Concern gives credibility to the process and will make the regulation consistent with statutory mandate. The Department indicates that they will identify approximately 185 Chemicals of Concern for the initial focus of the program through 2016 representing the most severe hazard traits. We strongly support the wisdom of starting with a manageable number of chemicals which the Department will identify based on chemical hazard information together with indicators of exposure. This is a critically important step; DTSC's identification of a focused, core group of substances will allow the Department to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace.

Moving beyond the commencement of the program, there should be a periodic (and transparent) process by which the Department identifies a narrowed list of chemicals on the basis of hazard and indicators of exposure. We recommend the following approach to prioritize Chemicals of Concern to a narrowed and focused list:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes. Provide opportunity for stakeholder input and comment (specific recommendations below);
- Merge those lists to generate a set of "Chemicals of Interest;"

---

<sup>10</sup> Not all chemicals require inclusion on the TSCA Inventory, as specified in the exclusions to TSCA (TSCA § 3(2)(B)) and exemptions from Pre-Manufacturer Notification requirements (TSCA § 5(h)(4)).

- Conduct an actual prioritization/screening to identify real Chemicals of Concern. This would encompass several steps:
  1. Remove from the merged list pesticides, pharmaceuticals, and other substances that are not chemical substances to which the regulation applies.
  2. Narrow the result from above to only those chemicals permitted in commerce in the U.S. using the TSCA Inventory of Non-Confidential Chemical Substances, publicly available on U.S. EPA's website<sup>11</sup>, and FDA and other exposure information such as Centers of Disease Control and Prevention (CDC) biomonitoring data<sup>12</sup>;
  3. Further narrow the result to chemicals that are in U.S. commerce in significant volumes using EPA and FDA information. The U.S. EPA's most recent publicly available data from the CDR Rule will identify all chemicals manufactured or imported into the United States at volumes >25,000 lbs. The CDR data reflect the most current, comprehensive snapshot of chemicals actively used in US commerce, and importantly, indicate the consumer product categories in which these chemicals are used. DTSC can also use the CDR data to identify chemicals for which respondents indicated use in products intended for children age 14 and younger.
  4. Publish the proposed Chemical of Concern list for public comment.
  5. Finalize the list.

As noted above, a variety of source lists are appropriate and will be useful as a starting point in a true prioritization process. We recognize and commend DTSC efforts to modify the previous draft of source lists to better represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment. However, there are several remaining concerns, as follows:

- (1)(C) is the European Union's (EU) endocrine disruptor list. The European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), the EU's most prestigious scientific body for toxicity testing, discredited this work because initial compilation of the list did not include a deliberative scientific process with opportunity for stakeholder input. Additionally, there is no conclusion on adverse impact, and therefore the listed chemicals may or may not be endocrine disrupting. Endocrine activity is not a distinct toxicological end point per se, but rather a measure of a chemical's ability to interact with components of the endocrine system. We recommend DTSC drop the EU list, with the assurance that chemicals identified as reproductive or developmental toxicants will capture chemicals that disrupt the endocrine system.

---

<sup>11</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>

<sup>12</sup> <http://www.cdc.gov/biomonitoring/>

- (1)(H) is Canada’s prioritization list of potential Persistent, Bioaccumulative and Inherently Toxic (PBT) compounds, completed in 2007 and mostly based on modeling results. Since that time Environment Canada has conducted hundreds of assessments in its Chemical Management Program leading to determinations in a number of cases that a chemical is not PBT. The Department should adopt the Chemical of Interest and Chemical of Concern lists utilizing the most up-to-date information from Environment Canada.
- (1)(I) is the International Agency for Research on Cancer’s (IARC) Carcinogen list. The IARC Group 2B list is comprised of substances for which there is limited human evidence and insufficient animal evidence of carcinogenicity.<sup>13</sup> DTSC should not include IARC Group 2B as a Chemical of Concern source list in the final rule.
- (1)(L) is the Office of Health Assessment and Translation reproductive and developmental toxicants. While we agree that this is an authoritative source, DTSC should only reference those chemicals identified by this Office as “Serious Concern” and “Concern.”
- (1)(N) The Washington State PBT list did not use criteria consistent with the US EPA PBT list and should be removed.
- (2)(F) is the California Biomonitoring program that remains in early stages with little completed (or validated) testing. DTSC should not consider listed chemicals in this program that are beyond the scope of the CDC Biomonitoring program and have yet to be studied as those having “exposure information.”
- (2)(H) The OSPAR list is not authoritative. Initial compilation of this list did not include a deliberative scientific process or opportunity for stakeholder input.

**§69502.2(b) - Additions to the Chemicals of Concern List.** The narrative standard for identifying additions to the Chemicals of Concern list is not sufficiently transparent. The Department needs to provide additional clarity to this process so that it is objective and repeatable if conducted by different sources. There is no indication what sorts of thresholds for the factors would be used in selecting additional Chemicals of Concern.

### **Article 3 - §69503 Product Prioritization**

As discussed in every P&G submission to DTSC throughout the development of the regulatory framework for the California Green Chemistry Initiative, we continue to fully support and strongly recommend a science-based prioritization process for Priority Products. Such a process would require the Department to evaluate hazard and exposure in prioritization actions to focus on those situations with the greatest potential for

---

<sup>13</sup> World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, p. 23.

significant exposures to the Chemical of Concern used in product in a quantity that can result in adverse public health or environmental impacts.

We recognize that the Department has made a number of improvements in this section over previous drafts and we support the continued inclusion of the following elements in the final rule:

- Consideration of both hazard and exposure to set priorities
- The focus on real health and environmental concerns over theoretical exposure
- The inclusion of “frequency,” “extent,” “level” and “duration of exposure” in §69503.2(a)(1)(B)(4)(c) which describes the approach for quantifying exposure in use and end-of-life scenarios
- The tightening of Key Prioritization Factors and requirement that Chemical of Concern/Priority Product pairs must meet both criteria of (1) a significant ability to contribute to or cause adverse public health and environmental impacts AND (2) a significant ability for the public... to be exposed to the Chemical of Concern in product...
- The concept of a Priority Product Workplan outlining the Department’s direction for 3 year periods.

We encourage DTSC to give greater attention to quantitative evidence of actual exposure (when available) in the prioritization process rather than rely solely upon indicators of exposure. Presence of a chemical in a consumer product is not the same as exposure, but simply presents a scenario where consumer exposure *may* occur. A number of additional factors contribute to actual exposure, including concentration of a Chemical of Concern in a Priority Product, accessibility to the Chemical of Concern during product use, use patterns of the product, frequency and duration of use, and method and site of application. Presence of a Chemical of Concern in a Priority Product is only one piece of the exposure puzzle. Quantitative information demonstrating exposures at levels of concern must be a driving factor in prioritization decisions.

**§69503.2(a)(1)(B)(4)(b)(iii)** - Worker exposure is within the exclusive jurisdictional purview of Cal/OSHA, which occupies the field in ensuring and addressing exposures in the workplace. This subparagraph should be deleted in its entirety, as well as any other references in the regulation to “workers,” “worker exposure” or “workplace.”

**§69503.2(a)(2)** - The need for emphasis on quantitative information demonstrating exposure in the prioritization process provides reason to question the practicality of the Key Prioritization Factor that states “the Chemical(s) of Concern in the product have a significant ability *to contribute to* or cause adverse public health and environmental impacts.” The “contribute to” language suggests that DTSC consider aggregate and/or cumulative exposure potential of a Chemical of Concern to cause adverse impacts without providing any indication as to how DTSC will obtain or evaluate this information. The regulation needs to specify the

methodology and data with which DTSC will evaluate a Chemical of Concern as “contributing to” adverse impacts to remain as a Key Prioritization Factor in the final rule. The assessment of aggregate and cumulative exposures is very complex and currently lacks the guidance of available and validated scientific methodologies. For this reason, we urge DTSC to remove the “contribute to” language from the Key Prioritization Factor since aggregate and cumulative exposure science is not yet well established.

The proposed regulation has abandoned any focus on intentionally-added ingredients, which are those chemicals that manufacturers purposefully formulate in a product to perform a function. DTSC should not designate consumer products that contain Chemicals of Concern as Priority Products if the presence is due to typical low-level impurities in raw materials that are not a concern for safety and are not economically feasible to remove. A focus on chasing unintentional trace levels of chemicals will significantly diminish or eliminate the meaningful improvements in public health and environmental protection expected of the program. As in our previous comments to DTSC, P&G strongly recommends that DTSC consider only chemicals that are intentionally-added above the AA threshold level when making product prioritization decisions.

In selecting Priority Products, the Department should use a standardized product nomenclature system. We note that the ISOR makes reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing Section 69503.3(f). We agree that the GS1 GPC is the appropriate source for describing products and recommend that DTSC identify Priority Products at the Brick Level, consistent with the approach already implemented by the States of Maine and Washington in their children’s product regulations. DTSC should describe Priority Product categories at the Class Level for the purposes of the Department’s Priority Product Work Plan.

**§69503.5 – Alternative Analysis Threshold Exemption.** DTSC should eliminate the Alternative Analysis Threshold Exemption Notification process in favor of a risk-based, self-assessment process. OEHHA uses a risk-based, self-assessment process under the Proposition 65 (Prop 65) Safe Harbor provisions for companies to determine whether they have to provide a warning statement on the product label. This aspect of Prop 65 has been very successful and could serve as a model for the application of the AA Threshold Exemption provisions of the Safer Consumer Product Alternatives Regulation to minimize administrative burden.

**§69503.6 – Alternative Analysis Threshold Exemption Notification.** According to the requirements of this section, a manufacturer will need to substantiate an assertion in the AA Threshold Exemption Notification that a Chemical of Concern is *not* present in a Priority Product with “laboratory analytical testing protocols and results used to detect and measure the concentration of the Chemical of Concern in the product.” To complete this testing, a manufacturer must have the capability to develop and validate test methods that will be reliable for a particular formulation. Even when a validated test method is already available, the process to substantiate an AA Threshold Exemption Notification will be lengthy and cumbersome. Each notification will require testing with lab QA/QC protocols to produce data on all product variations, summarization of all data, management signature and approval, followed by submission to DTSC. This is particularly distracting in the current landscape of scarce, stretched resources and competitive business challenges that demand full attention on delivering the next big innovation. These R&D resources will need to be pulled away from

constructive work to demonstrate a negative – that a Chemical of Concern, with which we do not intentionally formulate, is not present in our product. Reliance on detailed specifications already in place with raw material suppliers to ensure our ingredients meet quality criteria should be sufficient information to use in a self-assessment process similar to the OEHHA Safe Harbor process discussed above. A manufacturer could provide DTSC with the information used to substantiate the self-assessment upon request.

P&G has consistently advocated for the inclusion in the proposed regulation of a 0.1% *de minimis* threshold for intentionally-added Chemicals of Concern in Priority Products. The Practical Quantification Limit (PQL) approach that appears in this proposal requires regulatory compliance for Chemicals of Concern at detection levels in a Priority Product. With continuously improving analytical capability and ever-lower detection limits, analytical labs can identify small and insignificant levels of trace chemical presence in consumer products. The exposure to such trace chemicals is infinitesimal at best; the control of which is meaningless in protecting public health. Threshold provisions are standard in a variety of international chemical and product safety laws. Europe's REACH chemical law applies a 0.1% *de minimis* level as a default, even to the so-called Substances of Very High Concern. The European Cosmetic Directive also includes a 0.1% *de minimis* level for over 1,300 carcinogens and reproductive toxicants. Worker and transportation regulations in Europe and North America and the U.S. chemical control statute, TSCA, also contain provisions that recognize a 0.1% *de minimis* threshold. We strongly encourage California to remain consistent with other national and international laws that recognize the logic that the low, but measurable, levels in consumer products do not create significant exposures that present a likelihood of harm.

The importance of a default *de minimis* provides certainty and predictability to the regulated community in terms of their compliance responsibilities. Without a default threshold, manufacturers are left confused as to whether they or their brands are within scope of the regulatory compliance obligations, forcing manufacturers to conduct unnecessary and expensive testing to detect trace chemical presence that has no bearing on objective safety but may tip them into compliance scope. That said, we do support the concept that DTSC should have the flexibility to adjust the default *de minimis* based on sound science and reliable information. Experience in the European Classification system (EC No. 1272/2008) is that 85% of the over 4,000 chemicals with classified hazards are bound by a 0.1% threshold; the EU has determined a different threshold level – sometimes lower, sometimes higher - for the remaining 15% of chemicals.

#### **Article 4 - §69504 Petition Process for Identification and Prioritization of Chemicals and Products**

We commend DTSC for including a petition process that allows the *removal* of Chemicals of Concern and Priority Products from the appropriate lists. However, we do not understand why DTSC has not extended this same policy to entire lists of chemicals. A petitioner may seek addition of an entire list of chemicals, but no allowance exists for a petitioner to request the reverse. DTSC should allow petitions to *remove* entire lists of chemicals as well.

We strongly assert that all petitions which DTSC deems complete and acceptable for merits review require public notice and comment prior to the Department's final decision whether to grant or deny the petition.

## Article 5 - §69505 Alternative Analysis

**Summary Comments.** The alternatives analysis process is essential for developing safe and innovative consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development (R&D) and product design processes. As we have shared repeatedly with DTSC, P&G designs safety into our product development process right from the start. We incorporate green chemistry thinking and screen potential new ingredients for severe hazard “show stoppers” as a preliminary step to narrow the field of potential candidate ingredients to those that show promise for further assessment. Our research then proceeds with evaluation of the technical acceptability of candidate ingredients; with the gathering of more information on the hazards of the chemicals, the planned uses and anticipated exposure pathways; and the completion of a refined risk assessment to make final decisions about the ingredients we will use in our trusted brands. This risk assessment process is based upon an informed evaluation of both the hazard of the candidate ingredient and the anticipated exposure consumers will experience upon use of a product in which the ingredient is formulated. We assimilate robust information into the safety assessment that we have gathered on the hazards of the chemical, toxicity study data, intended use and application of the finished product, and world-leading understanding of observed consumer habits, practices and preferences to fully understand and anticipate the risk profile of each new ingredient. Only after we have assured ourselves of the safety of a new ingredient and the finished product in which it is formulated, do we move forward with marketing and scale operations to send the product to market.

A rational alternatives analysis process in a regulatory framework that parallels the key evaluation and decision approaches in the R&D and product design processes is essential from a business perspective. Such a framework must provide the opportunity for a manufacturer to fully demonstrate the safety of a Priority Product as an initial step before proceeding with an analysis of acceptable alternatives. It is this piece of the regulatory framework to which we see too little attention applied in the proposed regulation. Rather, the proposed regulation is threaded throughout with an emphasis on the search for alternatives to Chemicals of Concern and to “maximize the use of alternatives of least concern.” “Alternative” by virtue of the DTSC definition in Article 1, means a change selected from possible options. P&G contends that “no change” is an equally probable conclusion for a Priority Product after a risk-based evaluation of hazard, use and exposure. DTSC’s failure to fully appreciate and equally consider “no change” as a completely acceptable outcome will deny California consumers the continued freedom to choose products that they have come to know and trust to meet performance expectations, and the real possibility that California will miss opportunities to experience meaningful environmental benefits delivered by sustainable innovations.

DTSC must not create a regulatory AA process in which the Department compares manufacturers’ AA reports and chooses a particular alternative to mandate across industry. Every product has unique formulary chemistry and attributes, and a decision that a single alternative is the best solution for all products within a single category will be the wrong decision. Rather, DTSC needs to evaluate AAs based upon their own merits and compliance with the statutory requirements. A manufacturer has met their statutory obligation when they

complete and submit an adequate AA within the mandated timeline. The choice of the most technologically and commercially feasible alternative needs to remain solely with the manufacturer, who is the most informed entity capable of judging such feasibility within their unique business model.

**Positive Elements to Retain in the Final Rule.** We are pleased to see elements within the Alternatives Analysis section of the proposed regulation that are consistent with counsel we have provided DTSC over the years based on our experience with life cycle thinking and alternatives analysis. Positive elements that appear in this section and which DTSC should retain in the final rule include the following:

- Recognition that the design and conduct of an AA can pull from a number of available tools and methodologies. We commend the Department for allowing flexibility in a manufacturer's approach to the structure and completion of an AA for a Priority Product.
- Opportunity for a manufacturer to submit an abridged AA report when a "functionally acceptable" alternative is not available and further evaluation is not useful. We recommend DTSC allow a manufacturer to use the abridged AA path to demonstrate the Priority Product's safety and overall acceptable risk profile. This will allow a manufacturer to avoid the cost and significant resource allocation of the AA process that will deliver a reformulated Priority Product comparable in safety profile to the original formulation, but with trade-offs that could equate to inferior quality.
- The allowance for individual chemical manufacturers and/or formulators to complete an AA for a Priority Product or to join with industry partners in a consortium that represents an industry segment or an entire industry. Such an allowance will minimize resource expenditure, streamline administrative burden and allow manufacturers to share and build upon subject matter expertise and best practices.
- Recognition that multiple factors influence the decision-making process and ultimate selection of a technologically and commercially feasible alternative. Such a holistic analysis is needed to minimize potential trade-offs (both known and unintended) and avoid missed opportunities. The safety, compatibility, effectiveness, life cycle contributions, sufficient commercial availability, cost, compatibility with manufacturing lines, and likely **consumer acceptance** are all very relevant and appropriate considerations in an alternatives analysis. We thank the Department for listening and responding to our consumer insights and experiences that prove consumers generally will not accept trade-offs in product performance or an increase in price of their trusted brands after reformulation with an alternative. Without consumer demand, there will be no meaningful improvement in public health or environmental benefit because consumers will not replace existing products or practices with the new alternative. Instead, we have found that, when trade-offs occur, frustrated consumers will often resort to approaches such as "homebrew" concoctions or other practices that increase the risk of harm or injury. P&G commends the Department for understanding that the AA process must

include steps to identify and weigh all of these multiple factors to create a workable, practical, and meaningful Green Chemistry program in California.

- Acknowledgement that manufacturers have expert, in-house practitioners with a wealth of experience in AA and life cycle thinking who are fully capable of serving as Lead Assessors for the AA on their company's Priority Product. DTSC rightfully acknowledges that experienced practitioners understand available AA methodologies and tools from which they can choose to apply in a focused AA. The provisions allow these Lead Assessors to focus an AA on the critical parameters within a multi-factorial evaluation matrix that truly drive an alternative decision for a product. The familiarity with a manufacturer's Priority Product formulation allows an in-house practitioner to streamline resource expenditure and make the best selection of alternatives to minimize unacceptable trade-offs and/or risk for California consumers and the environment.
- Allowance for the Priority Product manufacturer to make the ultimate selection of an acceptable alternative based on findings during the AA process and best fit within their unique business model. DTSC will review AA reports for completeness and statutory compliance and implement a regulatory response, for which the Priority Product manufacturer can make recommendations as part of the final AA report. The way in which DTSC has constructed the proposed AA provisions demonstrates to us their appreciation for a manufacturer's informed decision-making process to achieve effective results.
- Inclusion of an Implementation Plan in the final AA report that provides a manufacturer with some flexibility to tailor the time needed to implement an alternative (including the steps necessary to ensure compliance with other federal and state laws).

**Opportunities for Improvement in the Final Rule.** While we acknowledge the many thoughtful improvements DTSC has incorporated into the AA provisions in response to industry outreach and dialogue, we continue to believe the proposed rule contains certain challenges to a practical and effective AA process for California's regulatory framework that require attention and modification for the final rule. From our decades of experience with alternatives analysis, we offer the following recommendations to ensure the AA construct for California establishes a workable process with realistic expectations and maximum opportunity to achieve Director Raphael's vision of meaningful (and measurable) improvements in public health and environmental protection:

1. **Codify the expectation that a "functionally acceptable" alternative encompasses consumer acceptability, compliance with legal requirements and delivers a finished product that meets or exceeds performance of the original Priority Product.** "Performs sufficiently well" (see §69501.1(a)(31)(B)) is not an acceptable criterion for a functionally acceptable alternative because the weak language suggests a lower or mediocre level of product performance and some level of trade-offs. As discussed earlier, consumers are not willing to accept trade-offs in performance and price; therefore, a "functionally

acceptable” alternative can only be one that does not change or improves the consumer’s experience. Otherwise, market economics will de-select the alternative and the program will fail to deliver any meaningful improvement in public health or environmental protection, following a significant expenditure of resources (both of the manufacturer and DTSC).

- 2. Incorporate reasonable timeframes for preparing AA reports.** The current allowances in the propose regulation (i.e., six and 12 months for preliminary and final AA reports, or 60 days and 18 months for AA workplan and final reports) are not practical. These tight timelines will prove unworkable should there be a need to do further experimental research to evaluate a particular alternative or development of a consortium or public-private partnership approach to accomplish the AA work.

A manufacturer will need more than 18 months to identify one or more functionally acceptable and commercially viable alternatives. The reality is that industry has already completed the “easy” alternative substitutions. A new alternative analysis will require several steps that illustrate the complex, lengthy process a manufacture undertakes to identify and implement a functionally acceptable and commercially viable alternative. The process begins with laboratory research by formulary scientists to identify possible alternatives that will function as intended and remain stable and compatible within the product formula matrix. The scientists work closely with toxicologists who assess and compare the safety profiles of the original product and potential alternative formulations. Once the manufacturer identifies a viable alternative (a discovery and development process that can require 3-5 years or more), the manufacturer will conduct market research to gauge consumer acceptance and identify any unforeseen trade-offs before selecting the most viable alternative. Consumer research is an iterative process that begins with laboratory-made samples but progressively advances to realistic prototypes produced from manufacturing pilot runs, an extensive operation which requires scale-up (and possible re-tooling) of manufacturing lines. Importantly, any step along this lengthy process can (and often does) reveal failed alternatives that can send the process back to the beginning.

Our experience with the product development process indicates that a “simple” chemical substitution in a formulated product requires a minimum of two months to coordinate scientists and engineers in the lab; one year of research to find a material that meets safety requirements, economic constraints, sufficient supply quantities, etc.; three months of process lab testing; six months for testing at the manufacturing plant (which requires scheduling of an experimental run since plants typically run at capacity); three months of consumer testing (not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). At least 26 months are necessary to complete the R&D process from the time one or a few materials are identified for further assessment. This timing holds true **only if** the identified alternative is acceptable for commerce in the United States. If the alternative is a new chemistry, the product manufacturer will likely have to submit a TSCA Pre-Manufacture Notification (PMN) to EPA, or enlist the chemical supplier to submit the PMN. With this additional federal compliance requirement, the needed timing to complete an AA extends to at least three years. (EPA may request additional data generation during review of a PMN that could extend the

standard 90-day EPA review period. For this reason, it is important that DTSC provide an option for a manufacturer to request an extension of the allowable AA timing.)

In most situations, chemical substitutions with acceptable alternatives will be much more complex than the aforementioned “simple” substitution. Substitution of a single Chemical of Concern may require multiple substitute alternatives if the Chemical of Concern performs different functions within the product formula matrix. A good example of this scenario is the replacement of phosphate in auto dishwashing (ADW) products. The replacement of phosphate required four to five different materials (depending on the ADW formulation) and initially took three years to complete. P&G’s experience with phosphate replacement in Cascade ADW required submission of a TSCA PMN in the United States and two New Substance Notifications (NSNs) in Canada, in compliance with the requirements of the Canadian Environmental Protection Act (CEPA). While ADW products sold broadly through the United States are now phosphate-free, manufacturers continue work to optimize the nil-P formula to improve cleaning performance that declined somewhat upon replacement of phosphate with alternatives.

The lengthy R&D process is one scenario that demonstrates the impractical timing expectation for completion of an AA in the proposed regulation. In some situations, a collaborative approach (e.g., consortium, trade association, public-private partnership) is the most efficient way in which to identify alternatives. Anti-trust requirements in the United States demand careful attention in building such a collaborative, including communication oversight by a third party. It can take three to four months to build an industry consortium before any analysis begins of a potential alternative(s) for a Chemical of Concern in a Priority Product. DTSC should incorporate flexibility into the timing expectations of the AA analysis and report submission deadlines when responsibility for the work falls to a collaborative. The logistics of the collaborative will undoubtedly slow the pace of the Stage 1 and Stage 2 analyses and necessitate expanded timelines in the final rule for a collaborative. DTSC should consider the inclusion of a provision in the final rule that allows a collaborative to form within one year of the Priority Product listing prior to the start of the AA clock.

In summary, the six and 12 month timings for the AA process in the proposed regulation are not practical or workable to account for a manufacturer’s R&D process or development of a coordinated collaborative under appropriate anti-trust auspices when an alternative is not readily available or identified. DTSC needs to expand the regulatory timeframes to a minimum of 12 months for a preliminary AA report and 24 months for a final AA report when an individual manufacturer conducts the AA, and 18 months/30 months for a collaborative approach to an AA.

- 3. Focus on Designated Chemical of Concern and Alternatives.** A single Chemical of Concern (CoC) should serve as the basis for designating a Priority Product and for the AA process. The proposed regulation provides no limitation on the number of Chemicals of Concern that could serve as the basis for designating a Priority Product, provided that collectively the Chemicals of Concern exceed the AA threshold. The comparative analysis of all potential alternatives for each Chemical of Concern in the Priority Product

would quickly become an overwhelming task and significantly compromise any chance of delivering a technologically and commercially feasible finished product that meets the consumer acceptance criteria and results in meaningful improvements in public health and environmental protection.

**4. Make consumer acceptance explicit among the factors listed in §69505.4(a)(2)(B).**

**5. Enable a process to “declassify” a Priority Product once the AA process and subsequent regulatory response implementation result in definitive results.** We urge the Department to narrow their focus to Chemicals of Concern/Priority Product pairs that truly contribute to significant adverse public health and environmental impacts, and for which an AA would be beneficial and would improve the safety profile for public health and the environment. When definitive results have been achieved, the Department should declare success and move on to other Priority Products and not leave the “Priority Product” designation attached to a manufacturer’s product. The value chain may perceive the persistence of such a moniker as cause for de-selection or other undesirable market pressures.

**§69505.4(a)(2)(C) - Economic Impacts.** Accounting for all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered to include, among others, costs to government agency, public, waste and end-of-life management costs is so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Moreover, traditionally, it is the responsibility of the government and not the manufacturer to assess the macro/micro economic impact of regulations as it is government and not industry that is responsible for making public policy decisions. More clear and concrete criteria need to be established by which the manufacturer understands what is required to satisfy this provision. As of today, there are no well-established methodologies that are able to properly assess these types of costs to enable rigorous and meaningful comparisons across all of the A-M elements. The methods are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well-being of Californians or their environment.

**§ 69505.4(b) Comparison of the Priority Product and Alternatives.** DTSC requires disclosure in this provision of all of the product development thought process (e.g., metrics used to evaluate alternatives, weights applied to the various factors, and ultimate selection of an alternative). These decisions are value judgments, are the fundamental underpinnings of business innovation and are different company to company. The Department must ensure that this sensitive trade secret information is protected. However, assurances are lacking in the proposed regulation since §69505.5(a)(6) states, “The responsible entity shall maximize the scope of information in the AA report that can be made available to the public, while maintaining protection of legitimate trade secrets.”

## **§69505.5 - Alternatives Analysis Reports.**

### **§69505.5(i)(2)(C) and §69505.5(j)(2)(C) - Focus on Designated Chemical of Concern and Alternatives.**

Sections that reference the need for a complete list or analysis of all chemical ingredients within the Priority Product beyond the designated Chemical of Concern should be deleted. A list of other chemical ingredients in products is not necessary for the successful analysis of the Chemical of Concern and its alternatives. The intent of the statute is not ingredient disclosure for Priority Products; rather, the regulation should remain consistent with the statute and focus on assessment of the identified Chemical of Concern and its alternatives, NOT all chemicals within a product.

**§69505.5(k)(2)(A) - Compliance with law.** Within the Implementation Plan the proposed text refers to any steps necessary to ensure compliance with applicable federal, state, or local laws. This provision should be expanded to include international laws as well. Since companies operating within the U.S. often make and market products for all of North America, compliance with Mexico and Canada's requirements may also be necessary (e.g., a NSN in Canada).

**§69505.5(k)(2)(B) - Focus on Designated Chemical of Concern and Alternatives.** The manufacturer's proposed regulatory response should focus on the outcome related to the specific Chemical of Concern/Priority Product pair that drove the AA. All language relating to Priority Product's contents beyond the Chemical of Concern that was the basis for the listing should be deleted from this Article. We propose revision of the language in this section as follows:

"The implementation plan may also include the identification of any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, ~~any the~~ **Chemical(s) of Concern, that is/are the basis for designation of a product as a Priority Product**, that will be in the selected alternative or that is in the Priority Product **above the AA threshold** if the decision resulting from the AA is to retain the Priority Product."

## **Article 6 - §69506 Regulatory Responses**

**§69506 - Regulatory Response Selection Principles.** Subdivision (a) provides that the Department shall identify and require implementation of regulatory responses that "maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible." Subdivision (b) provides that in selecting regulatory responses, the Department shall give preference to responses "providing the greatest level of inherent protection." Inherent protection is defined to mean "avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls."

This provision amplifies our concern expressed earlier in these comments that the proposed regulation has a clear persuasion for substitution with an acceptable alternative rather than first applying equally due consideration that a Priority Product may be completely safe as it currently exists with no change. When a manufacturer can clearly demonstrate the objective safety of a Priority Product, it is neither practical nor meaningful to expend significant people and financial resources to chase “safer” with no measurable improvements in public health or environmental protection.

**§69506.2 - AA Report Supplemental Information Requirements.** This section provides that the Department may, at any time, require a responsible entity to provide information supplementary to the final AA report for the Department to select and ensure implementation of one or more regulatory responses or to fill one or more of the information gaps identified in the final AA report. This section contains no standards by which the Department will make a decision to require supplementary information in order to evaluate an initial regulatory response and instead provides complete, arbitrary discretion to the Department. We request that the final rule contain specific standards or criteria against which DTSC can make such an information request to provide greater regulatory certainty to the regulated community. We make this same request for inclusion of standards or criteria in the final rule that will govern DTSC’s selection from the various regulatory response options listed in Article 6.

**§69506.4 - Product Information for Consumers.** This section, in summary, applies to all products going through the AA process for which implementation of the acceptable alternative has not yet occurred. The requirements of this section task a manufacturer with making substantial information available to consumers prior to exposure to any Chemical of Concern via the manufacturer’s website and through product packaging or written materials accompanying the package, or by a retailer’s action to post information in a prominent place at the point of retail display. Consumers are now accustomed to reviewing manufacturers’ websites for ingredient disclosure information, for safety information about product ingredients, to obtain a Material Safety Data Sheet (MSDS), and to review positive CPSC certification statements that attest to a product’s compliance with applicable U.S. regulations, rules, standards and/or bans. Additionally, a product label directs consumers to the manufacturer’s website or to a toll free 1-800 phone number from which consumers can obtain the same ingredient and product safety information. A requirement to add the same information on a product label about the Chemical of Concern and current, “in progress” AA status of a Priority Product is redundant with information that will be available to consumers through website or telephone access. Finally, a manufacturer has much more flexibility to add more detailed context to a website to help a consumer understand the reason for and meaning of communicated information required by this regulation than a small product label with limited space. Website communication will allow a manufacturer to also quickly respond to a change in the AA status of the product or provide updated context to consumers for any type of mandated regulatory response. In contrast, a change to product label artwork requires (at a minimum) 12 weeks to complete, which could create a situation in which the information communicated to consumers on product labels is out of step with the current regulatory status of a Priority Product in California.

DTSC relies upon their website for communication to the public of certain actions and information collected under this regulation; we ask that the Department extend this same allowance to manufacturers for consumer communication.

**§69506.8 - End of Life Management Requirements.** The California Department of Resources Recycling and Recovery (CalRecycle) is the state's leading authority on recycling, waste reduction and product reuse. As such, CalEPA authorizes CalRecycle to develop and implement end-of-life management programs, such as Extended Producer Responsibility (EPR) programs identified as "product stewardship programs" in this section of the proposed regulation. The authority provided to DTSC in this section to designate an end-of-life regulatory response is a clear example of regulatory duplication, which is prohibited by statute. At most, DTSC can propose end-of-life management actions to CalRecycle, the Department with authority to administer such waste programs in the state.

**§ 69506.9. Advancement of Green Chemistry and Green Engineering.** This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals, all of which would supplant the manufacturer's existing product in the market. Once again, no standards are provided to indicate when DTSC could apply this regulatory response. The provision that requires funding of a challenge grant is frankly absurd unless legal protections are in place to ensure ownership of the intellectual property. The funding could directly support a third-party stakeholder who would benefit from the market exit of a manufacturer's Priority Product. It is conceivable that the recipient of the challenge grant could design a "green innovation" to specifically capture the market share of the original Priority Product. As written, there is no indication in this section that the intellectual property or other ownership rights of the resulting technology would return to the original manufacturer. If the recipient of the challenge grant were free to prosper from the "green innovation" that emerges from his/her research, DTSC would essentially have the authority under this proposed regulation to require a manufacturer to fund itself out of business. This provision basically violates every economic principle of a competitive free market. We strongly implore the Department to remove this provision in its entirety from the final rule.

**§69506.11 - Exemption from Regulatory Response Requirements.** Section 25257.1(b) of the statute provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides that, "The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

This section of the proposed regulation puts the burden on the responsible entity to apply to the Department for an exemption from regulatory response requirements based on a conflict with or substantial duplication of one or more requirements of another California or federal regulatory program. Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department from superseding, duplicating, or adopting conflicting regulations. The Legislature imposed responsibility on the Department to implement that provision.

**§69506.12. Regulatory Response Report and Notifications.** This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. Section 25253(b) of the statute provides that the regulations shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. In the proposed regulation, the Department does not designate notification to retailers as a regulatory response. Rather, the proposed regulation applies the notification requirement to a responsible entity *after* DTSC imposes a regulatory response on that entity. Nothing in the statute authorizes the Department to impose such a notification requirement after DTSC specifies a regulatory response required of the responsible entity.

#### **Article 7 - §69507 Dispute Resolution Process**

This section divides the various regulatory response procedures that appear in Article 6 into those for which formal dispute resolution procedures apply and those for which informal dispute resolution procedures apply. All final regulatory decisions and actions that DTSC employs following completion of the AA process for a Priority Product should be subject to **formal** dispute resolution procedures in the final rule. The regulated community has a right to establish an administrative record relative to an objection to a final Department regulatory action, and to escalate the objection to judicial review upon unsatisfactory administrative dispute resolution.

Similarly, the regulated community asserts that a formal dispute resolution process is needed for Department decisions made under Article 2 (Identification of Chemicals of Concern), Article 4 (Petition Process for Identification and Prioritization of Chemicals and Products) and Article 10 (Trade Secret Protection). The proposed regulation indicates that for these three Articles, a dispute would be debated in a court hearing as part of a judicial review process. A formal dispute resolution process will allow the establishment of an administrative record and opportunity to narrow scope of the dispute and exhaust administrative remedies prior to the judicial review process.

Article 7 describes a 30-day time period following “the notice or website posting of a Department decision” in which a responsible entity has the opportunity to initiate a dispute resolution process with the Department. Since 30 days is a relatively short window of time, it is critically important that the regulated community clearly understand when the “time clock” begins. For example, if the Department issues a decision via written notification, does the 30-day time period begin upon the date of the Department’s mailing or upon the date a responsible entity receives the mailing? If the Department will post decisions on their website, will there be some sort of alert to the regulated community to look for new information on the DTSC website? Section 69507.6(b)(1) shows yet another example where more specificity is needed – what sort of timeline can a responsible entity expect for compliance when the Department responds to a Request for Review? The Department needs to provide these logistical details in the final rule to set clear expectations for the regulated community and to ensure responsible entities have a thorough understanding of their rights under the dispute resolution process.

Finally, we request DTSC clarify the scope and intent of the “stayed during the pendency of an administrative dispute” language in §69507(d). Are all compliance actions described under the proposed regulation stayed from the date a responsible entity initiates a dispute with the Department to the date on which the parties resolve the dispute? As an example, is a manufacturer responsible for the consumer and retailer notification obligations for a Chemical of Concern in a Priority Product during the period of dispute examination?

#### **Article 8 - §69508 Alternative Analysis Certification**

**§69508 – Certified Assessors.** Practicing, in-house company experts with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead AA projects for product development. AA is a broad process that must evaluate a number of holistic considerations for any potential chemical alternative, including impact on safety and product performance, potential interaction with other formula components, useful life, other environmental criteria, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right combination of chemical ingredients for consumer product formulations. In-house company experts understand the intricate R&D science invested in developing consumer product formulations, have access to a variety of available subject matter experts, and have the necessary, in-depth understanding of consumer behavior and preferences to lead the holistic AA evaluation process. In-house company experts have a wealth of “hands-on” experience with life cycle thinking and alternatives analysis and need not complete the classroom training and continuing education classes for certification, as specified in this section.

**§69508.1 – Qualifications for Accreditation Bodies.** Due to the complex nature of any AA, the availability and accessibility to a wide range of expertise in various scientific fields are instrumental to a successful accreditation body. Broad skills and knowledge are required to conduct analysis across the extremely broad spectrum of products, chemicals, evaluation factors and impacts that would need to be assessed in the AAs envisioned by this proposed regulation. We ask DTSC to include exposure assessment as an area of practice in 69508.1(a)(5) since it appears this section omitted this important field of expertise. Key technical skills beyond exposure assessment that are required to develop safe and effective products for consumer use include toxicology, environmental toxicology, chemistry, chemical engineering, microbiology. In addition, the process will require the help of those knowledgeable in finance/accounting, life cycle analysis, and consumer and clinical testing.

The accreditation body should focus on training would-be assessors as project managers. The certified assessor should only be responsible for ensuring that all expectations and requirements for the AA have been addressed and the overall AA conforms to regulatory expectations. The certified assessor should rely on subject matter experts in the various fields and disciplines to provide the necessary information on relevant factors within an AA.

## Article 10 - §69510 Trade Secret Protection

Protection for Trade Secrets and Intellectual Property is a critical concern of the regulated community as California embarks on implementation of the Green Chemistry Initiative. The statute and this proposed regulation have rightfully made trade secret protection a core component of this program, and DTSC is supported in this effort by existing California statute and regulations. However, the proposed regulation includes several elements that conflict with and/or exceed statutory authority as detailed below.

As a threshold matter, we join our industry partners in emphasizing that product formula information is a trade secret and critical part of a company's intellectual property. A product formulation can reveal the "recipe" of flagship brands that provide decades of market success for manufacturers. While we understand the public's interest in formula ingredient information, this public interest requires a careful evaluation and balance with trade secret protection in a competitive market. Disclosure of seemingly isolated pieces of information about a product formula, including ingredient chemical names, concentrations, CAS RNs, and physicochemical properties, provide key "clues" to a trained eye to unravel sophisticated formulary science in which a manufacturer made a significant R&D investment to create. Product formula disclosure will forever present a concern to consumer product manufacturers because of the very real threat of competitive surveillance. Loss of intellectual property to competition in California prevents a manufacturer from obtaining confidentiality protection for that formula anywhere else in the world. This is very problematic for a manufacturer who intends to expand in other geographies as part of an overall global market strategy. The inability to protect formula information as confidential business information as a manufacturer enters a new market can result in a subsequent quick market entry of "knock-off" products from competitors. These competitors reap the economic benefit from marketing the innovation without investing the significant R&D capital as the original manufacturer. This dynamic showcases the challenge that domestic manufacturers face in the global marketplace and the very real threat to loss of U.S. leadership in the manufacturing sector.

We fully understand our consumers' interest in the science and safety behind all of our brands that they use in their homes and around their children on a daily basis. P&G and many of our leading industry partners have made information available and easily accessible on our corporate websites for consumers interested in learning more about our product ingredients, our product safety program and our environmental stewardship commitments. We are always willing to discuss safety questions or inquiries about specific ingredient content with our consumers when they contact us, and we routinely provide full formula disclosure and MSDSs to Poison Control Centers across the nation to respond to medical emergencies. We have a very sophisticated post-market surveillance system to monitor consumer experience with all of our products and we use insights from this work to continuously improve our products to delight our consumers by touching and improving their lives. We are fully committed to ensuring the health and safety of all of our consumers and take this core responsibility very seriously when determining which information is most helpful to make available on our product labels and websites.

The public right-to-know agenda has effectively characterized consumer product manufacturers as "hiding" important information as secrets. This is an unfair characterization considering the many opportunities we

provide our consumers to learn more about our operations and the science and safety behind our brands so that they feel informed and assured during product use. However, it is true that we and our industry partners carefully balance transparency actions with the critical need to protect our confidential business information from competition in a global marketplace.

Therefore, it should come as no surprise that substantial portions of AA reports will require trade secret protection. Detailed, data-based comparisons of Chemical(s) of Concern and potential alternatives will reveal how those ingredients interact with the formula matrix to deliver desired results. This is key information that, if disclosed by DTSC as part of a public transparency focus during program implementation, will decode confidential formulary science to competitors.

We also strongly oppose the new provision in §69510.(a)(12)(f) that prevents protection of chemical identity when that information is contained in any hazard trait submission. This is unnecessary, considering that the public can interpret hazard trait information independent of a specific chemical identity, and exceeds the Department's authority under the statute. We fully support the written comments provided by the American Chemistry Council that discuss the sufficiency of generic chemical names in association with hazard trait information to meet statutory requirements and to enable an appropriate level of information to the public for understanding the safe use of chemicals.

Disclosure of proprietary raw material considerations, compositions, processes, use methods, technology, etc., will potentially impact a manufacturer's patent rights. We support the written comments of the Grocery Manufacturers Association that explain the difficulty a manufacturer will face in the new "first to file" patent landscape in the U.S. and the complications that this proposed regulation will introduce with a strong focus on public disclosure of chemical and formula information.

**§69510 - Assertion of a Claim of Trade Secret Protection.** Subdivision (a) requires an entity making a claim for trade secret protection to provide specific substantiating information. We fully support a requirement in this regulation for upfront substantiation of trade secret protection claims. We believe the Department can further strengthen this requirement in the final rule by linking responsible entities' substantiation submissions to a commitment by the Department to review them. Currently, the proposed regulation provides no discussion or assurance that DTSC will review this information. Additionally, the proposed regulation provides no direction to a manufacturer on how to assert a trade secret claim when the manufacturer is bound by a Non-Disclosure Agreement (NDA) with a raw material supplier. This is a common scenario for which the Department will need to devise and elucidate a process in the final rule. For example, will the manufacturer have the responsibility to seek approval from the raw material supplier prior to submitting a trade secret claim to DTSC? Or will DTSC submit a written request directly to the raw material supplier to release the protection of the confidential information? These are important procedural details that will guide and clearly establish expectations for the regulated community under this section.

The criteria that DTSC list in this section for proper substantiation of a trade secret claim far exceed statutory authority. Paragraphs (1) and (2) in this section are the only criteria consistent with the language of the California Uniform Trade Secrets Act “UTSA” (Civil Code sections 3426.1-3426.11). The proposed regulation exceeds statutory authority and diverges from California UTSA in requirements presented in paragraphs such as (6), the estimated value of the information to the person and the person’s competitors; (7) the estimated amount of effort and/or money expended by the person in developing the information; (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering; and (10) a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed. This is a clear example that the proposed regulation before us is not legally defensible. The final rule should not contain any substantiating criteria that exceed statutory authority or are inconsistent with California Civil Code.

Subdivision (g) provides that trade secret protection may be claimed for the identity of a chemical that is the subject of a hazard trait submission only if the claim is for a proposed alternative to a Chemical of Concern in a Priority Product, subject to certain requirements. Those requirements include demonstrating to the Department’s satisfaction the chemical is a new chemical or a new use of an existing chemical, providing the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing Chemical of Concern of the Priority Product, and complying with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret. Finally, the proposed regulation provides no clarification to the regulated community of what constitutes a “new use,” for which DTSC and responsible entities may have vastly different interpretations.

**§69510.1 - Department Review of Claims of Trade Secret Protection.** This section is in need of greater clarity to ensure the regulated community understands expectations. For example, §69510.1(b)(1)(D) needs to specify a minimum period of time (no less than 30 days) by which a submitter needs to provide the requested information for equitable application. Section §69510.1(b)(1)(D)(2) and §69510.1(b)(1)(D)(2)(c) need to revise the Department actions until 30 days following receipt and signature of the DTSC notification sent to submitters via certified mail, since arrival time of the certified mail to the intended recipient may vary. Additionally, both sections need to recognize that a submitter may seek judicial review by filing an action for any type of relief appropriate under the law, not just preliminary injunction or declaratory relief.

Finally, the trade secret provisions under Article 10 need to clarify that trade secret protection can extend to review and AA involvement of external certified assessors and accreditation bodies (Article 8) and audit reports containing confidential business information (Article 9).

\* \* \*

## GCREgs@DTSC

---

**From:** Prutzman, Annie <aprutzman@bishopodowd.org>  
**Sent:** Monday, October 01, 2012 9:22 AM  
**To:** GCREgs@DTSC  
**Subject:** Toxic Substances Control

**Categories:** Comment

To Whom it May Concern:

I understand that by law, the Department of Toxic Substances Control (DTSC) is required to enact strengthened regulations for Safer Consumer Products. The purpose is to reduce the public's exposure to these chemicals and to the hazards posed by them. 1,200 toxic chemicals in consumer products that have been identified as a threat to public health. Stronger regulations of these dangerous chemicals that currently pervade our consumer products were supposed to have been enacted, according to the law passed in 2008, by January 2011. Here it is October, 2012, and your office has not done this yet! Why should the lives of my children and my grandchildren be illegally put at risk by the tardiness of your office? What is going on in your office? Have you backed down before corporate lobbyists?

These substances must be regulated and removed AS SOON AS POSSIBLE.

It is shocking that an agency that is supposed to follow the law is not doing so. DO NOT DILUTE THIS LEGAL PROTECTION! Please grow a stiffer backbone and face down the profit mongering chemical companies. The public relies on public agencies like yours to protect public health. Please do your job! The future of my children, my students, and all the people of California depends on you!

Sincerely,  
Anne Prutzman  
A California teacher

## GCREgs@DTSC

---

**From:** Allan Reynolds <ajreynolds3442@sbcglobal.net>  
**Sent:** Tuesday, October 02, 2012 11:36 AM  
**To:** GCREgs@DTSC  
**Subject:** chemicals

Where's the state's backbone? The legislators passed a BIPARTISON law in 2008 regarding an agreement to protect consumers from dangerous chemicals in the products they buy. The list was to be published in January 2011. Still not published and legislators "discussing" it with chemical companies who oppose it in Oct. 2012. We're talking about public health! Are campaign payments to legislators more important ? Please BAN these chemicals in all consumer products.

No wonder the California Legislator is held in such low regard.

Julia Reynolds - a voter for 58 years

# Etta+Billie

handmade sustainable bath and body products

October 9, 2012

Krycia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Dear Ms. Von Burg,

My name is Alana Rivera and I own a small bath and body company based in San Francisco called Etta + Billie. I am writing you to express my concern over the proposed California Green Chemistry Initiative. My company prides itself on producing natural handmade bath and body products and I am worried that the proposed legislation would negatively impact my company, along with many other small natural manufacturers and retailers. As the regulation stands, I am highly concerned about requirements to submit confidential business information, extensive paperwork, submission of potential trade secrets along with the identification process utilized to identify chemicals of concern. I truly believe that this initiative will negatively impact many businesses throughout the state of California.

I urge you to postpone the initiative until economic consequences and other concerns can be assessed and discussed.

Thank you for your time and consideration.

Best regards,



Alana Rivera  
Owner + Creator

415.297.5528  
[www.ettaandbillie.com](http://www.ettaandbillie.com)  
2615 21<sup>st</sup> Street, San Francisco, CA 94110

## GCREgs@DTSC

---

**From:** Carol Rowley <sally81800@yahoo.com>  
**Sent:** Monday, October 01, 2012 6:19 PM  
**To:** GCREgs@DTSC  
**Subject:** dangerous chemicals regulations

We need the stronger rules to regulate or eliminate dangerous chemicals in products for sale in California. Please do not stand in the way of public health.

Carol J Rowley  




**RUBBER**  
manufacturers  
association

1400 K Street, NW • Washington, DC 20005 • tel (202) 682-4800 • fax (202) 682-4854 • www.rma.org

October 11, 2012

Deborah O. Raphael  
Director  
Department of Toxic Substances Control  
1001 I Street  
P.O. Box 806  
Sacramento, CA 95812-0806

**RE: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

**I. Introduction**

RMA is the national trade association representing major tire manufacturers that produce tires in the United States, including Bridgestone Americas, Inc., Continental Tire the Americas, LLC; Cooper Tire & Rubber Company; The Goodyear Tire & Rubber Company; Michelin North America, Inc.; Pirelli Tire North America; Toyo Tire Holdings of Americas Inc. and Yokohama Tire Corporation. RMA members are affected by the proposed rule because they manufacture tires, a consumer product, available for sale or placed into the stream of commerce in the state of California.

RMA offers the following comments on the July 2012 Safer Consumer Products proposed regulation and thanks the California Department of Toxic Substances Control (DTSC) in advance for consideration of these comments. Cal. Code Regs. Tit. 22, § 55 (2012). RMA urges the Department of Toxic Substances Control (DTSC) to take the time necessary to revise this regulation to make it feasible for manufacturers.

**II. RMA supports DTSC's decision to include a delisting petition process; however, we have concerns about the timing of petition determinations by DTSC**

Article 4, Section 69504, enables a person to “petition the Department to evaluate a claim that a chemical or a product that contains a chemical should be delisted as a Chemical of Concern or a Priority Product.” (69504 (a)). As with most products available for sale in California, tires contain chemicals. However, the process of manufacturing a tire involves vulcanization, which changes the chemical composition of the chemicals formulated into the tire in the initial stages of the manufacturing process. As a result, the risk for exposure to chemicals in tires is reduced or eliminated as the chemicals in tire formulations undergo a chemical reaction

during the vulcanization or heating of a tire during the manufacturing process. RMA recommends that certain consumer products, such as tires, or chemicals present in consumer products at levels that pose no meaningful risk of adverse environmental or health impacts, should be removed from the list of Chemicals of Concern (CoC) and/or the list of Priority Products. The “early off-ramp” provided in the petition process will enable the Department to focus time and resources on the Chemicals of Concern and Priority Products that pose the greatest risk to the public.

While RMA strongly supports the inclusion of the petition process to list or delist a chemical or product, we are concerned about the timing for the Department to make determinations about whether to grant or deny a petition. The proposed rule indicates that “the Department shall make its determination no later than the next regular update of the Chemicals of Concern or Priority Products list.” (69504.1(a)). However, the proposed rule specifies that the Chemicals of Concern list shall be updated “periodically,” and the Priority Products list shall be updated at least once every three years. (*See sections 69502.3(a) and 69503.4(f)*). This creates an unreasonable situation in which a manufacturer may have to complete a preliminary and final Alternatives Analysis before a determination to grant or deny the delisting petition has been made. RMA recommends that a responsible entity should not be required to complete an Alternatives Analysis until the Department has issued a notice of their decision to grant or deny the delisting petition.

### **III. How the Safer Consumer Product Proposed Rule May Impact Tires**

#### **A. Impact on National Highway Traffic Safety Administration (NHTSA) federal safety requirements**

RMA is concerned that if tires are not granted an exemption from the regulatory response requirements of the proposed rule because of conflicts with federal law, the requirements for chemical substitution could jeopardize attainment of tire safety standards established by NHTSA. Section 69506.11 specifies that a responsible entity may request and receive an exemption from the requirements of the rule if the “required or proposed regulatory response would conflict with one or more requirements of another California or federal regulatory program or an international trade agreement with the force of domestic law, in such a way that the responsible entity cannot reasonably be expected to comply with both requirements.” (§ 69506.11(b)(6)(A)). In RMA’s view, this provision provides ample justification that tires should be exempt from the regulatory requirements of the proposed rule if removing or substituting a chemical conflicts with, or prevents meeting NHTSA motor vehicle safety standards.

Further, the proposal also specifies that “if the exemption request or the Department’s granting of the exemption is based solely on... conflict with another Federal regulatory program..., the Department may require implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.” (§ 69506.11 (d)). RMA recommends that if Federal law exempts a responsible entity from the requirements of the rule, DTSC should not require the responsible entity to submit any response.

The chemical ingredients in tires are present because they impart critical functions and the composition of tires cannot be modified without great care. All RMA members make tires that are safe. Changes in tire composition could affect critical attributes such as stopping distance, tire wear, tire fuel efficiency and other safety-related components. NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet Federal Motor Vehicle Safety Standards (FMVSS). Any change in the composition of tires typically requires feasibility studies and lengthy, multiple tests to ensure that the tires continue to meet FMVSS. If the Department requires tire manufacturers to substitute a chemical ingredient in tires with an alternative, and the use of the alternative chemical jeopardizes achievement of NHTSA safety standards, tire manufacturers may not be able to comply with both the proposed regulation and federal NHTSA safety standards.

#### **B. Impact on EPA's Corporate Average Fuel Economy (CAFE) Standards**

Corporate Average Fuel Economy (CAFE) standards were enacted by Congress in 1975 to reduce energy consumption by increasing the fuel economy of cars and light trucks. CAFE standards for cars and light trucks are established by NHTSA. The U.S. Environmental Protection Agency (EPA) provides NHTSA fuel economy data which NHTSA uses to set the CAFE standards. In regard to tires, low rolling resistance is an important attribute that automobile manufacturers require to enable them to meet fuel efficiency targets under the CAFE standards. Any change in tire composition required by the proposed regulation could affect tire manufacturers' ability to produce tires that allow new automobiles to meet the CAFE standards. If a chemical substitution required under the informal draft regulation jeopardizes CAFE standards, tire manufacturers may be unable to comply with both the proposed regulation and Federal law.

#### **IV. DTSC should include a petition process with criteria that responsible entities can submit to receive additional time to complete Alternatives Analysis (AA) reports rather than the one size fits all approach in the proposed regulation**

Again, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet National Highway Transportation Safety Administration Federal Motor Vehicle Safety Standards. Unlike chemicals that are added to a product for taste, color or appearance, the chemical ingredients in tires are present to ensure the safe and reliable function of the final product. The proposed rule specifies that preliminary Alternatives Analysis reports are due 180 days after the product is listed on the final priority product list, and final Alternatives Analysis reports are due 12 months after the date the Department issues a notice of compliance for the preliminary report. (§69505.1(c)(3)). Responsible entities can request a one-time extension from the Department of up to 90 days to complete the Preliminary or Final AA. (§69505.1(d)(1)). The proposal also specifies that entities can request up to a 36 month extension to submit a final AA report if additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives. (§69505.5(k)(1)).

RMA recommends that rather than specifying the maximum extension an entity can receive to complete the Alternative Analysis reports, that the Department grant extensions based upon a petition that demonstrates the need for additional time to enable Priority Products, whose

safety and performance are regulated by other state or federal laws, to complete safety and performance testing requirements. A case specific schedule, taking into account testing and certification procedures, is necessary, rather than the one-size-fits-all approach embodied in the current proposed regulations.

Tires are highly engineered products. The time needed to assess whether there is a workable chemical substitute for an ingredient in tires varies depending on the chemical that is to be assessed for possible replacement. Each component of a tire is composed of a different rubber compound. Compounds vary depending on the function of the compound and the type of tire that contains the compound. Thus, the type of tire that contains the Chemical of Concern, the size of the tire, the type of compound in the tire and the purpose of the compound in the tire, all affect the amount of time needed to determine if there is a viable substitution. Additionally, depending on the chemical that is to be assessed for a safer alternative, it is necessary to determine the ability of the rubber processing equipment to handle the compound that contains the new chemical.

**V. The proposed Safer Consumer Products rule must include adequate protection for confidential business information**

The proposed rule fails to provide adequate protection for confidential business information (CBI) and is inconsistent with the CBI practice followed by the National Highway Traffic Safety Administration (NHTSA) and the U.S. Environmental Protection Agency (EPA) for tires and tire manufacturing. For example, the proposed rule requires that certain information, such as “a list of, and all common names for, all Chemicals of Concern known to be in the product”, be made available to the public when an alternative chemical is not selected. (§69506.4(a)(1)(C)). This provision fails to recognize that the Chemical of Concern in the priority product may be CBI. Additionally, the proposal requires manufacturers to notify DTSC if their product contains a chemical of concern, and DTSC will post on its website the list of priority products that contain the Chemical of Concern. However, this approach also fails to recognize that the presence of a Chemical of Concern in a priority product may itself be considered a trade secret.

**A. NHTSA**

RMA recommends DTSC include categorical CBI protection for ingredients in tires that are trade secrets. NHTSA provides categorical CBI protection for various classes of early warning data required to be submitted under the TREAD Act. 49 CFR Part 512 Appendix C (2003). Examples of such early warning data for which categorical CBI protection is granted include data on production numbers, consumer complaints, warranty claims, field reports and common green tire identifier information. Common green tire information includes information regarding tires that are produced to the same internal specifications but that have, or may have different external characteristics and may be sold under different tire line names. Specifically common green tire data includes information on all relevant tire lines, tire type codes, stock keeping units (SKU) numbers, brand names and brand name owners. 49 CFR 579.26(d). NHTSA has granted categorical CBI protection for all common green tire information submitted to that agency. Information on common green tires is not available to the public and cannot be

derived from any public source. Furthermore, CBI protection for this category of information is necessary because disclosure of this information would cause substantial competitive harm to tire manufacturers since it would allow competitors to know with exact certainty which tires have the same specifications even though many are sold under different tire brand names.

NHTSA based its decision to classify categories of early warning data information as confidential, on the substantial competitive harm and impairment standards of the Freedom of Information Act (FOIA) Exemption 4. See 5 U.S.C. 552(b)(4); 49 CFR Part 512 App. C (2003). FOIA Exemption 4 specifies that information should be considered confidential if the “disclosure of the information is likely to have either of the following effects: (1) impair the Government’s ability to obtain necessary information in the future; or (2) cause substantial competitive harm to the competitive position of the person from whom the information was obtained.” *National Parks & Conservation Ass’n v. Morton*, 498 F. 2d 765, 770 (D.C. Cir. 1974). See also *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 51 (D.C. Cir. 1981). The test for whether release of the confidential information would cause substantial competitive harm is whether disclosure of the information would “likely” cause competitive harm, for whatever reasons. *McDonnell Douglas Corp v. U.S. Dept. of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004), see also *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 341 (D.C. Cir. 1989). One essential element is that the submitter has never released the documents to the public or to any third party. See *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 877 (D.C. Cir. 1992). Companies need not show actual competitive injury to qualify for the exemption. *Niagara Mohawk Power Corp. v. U.S. Dep’t of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999); *CNA Financial Corp. v. Donovan*, 830 F.2d 1132, 1152 (D.C. Cir. 1987). Further, FOIA Exemption 4 does not involve a balancing of competitive harm to the party that provided the information to an agency against possible societal interests such as research or provisions of information to the public.

The use of categorical CBI protection by NHTSA is also warranted by the Supreme Court’s decision in *Fed. Power Comm’n v. Texaco*. The Court in this case recognized that case-by-case decisions are not required if the use of categorical rulemaking would not be detrimental to the implementation of a regulatory scheme. *Fed. Power Comm’n v. Texaco, Inc.*, 377 U.S. 33, 44 (1964) (individual hearings for thousands of individuals who apply for certificates of public convenience and necessity under the Natural Gas Act would prolong and cripple the process of regulation).

NHTSA’s decision to grant categorical CBI protection for early warning data reduced the burden on the agency and manufacturers to complete and review CBI claims. If the agency required manufacturers to submit data confidentiality requests with each quarterly early warning data submission, it would have greatly increased the burden on industry and the agency to review the requests. Furthermore, providing categorical CBI protection also helped to eliminate the possibility for inconsistent decisions on the confidentiality of data submitted.

## **B. EPA**

The U.S. EPA provides CBI protection to specific chemical descriptions under TSCA. For example, under TSCA section 14, manufacturers and processors are permitted to claim as

CBI the specific chemical identity of a particular substance in connection with the TSCA inventory reporting requirements. TSCA section 14 prohibits EPA from disclosing confidential business or financial information submitted to the Agency under a claim of confidentiality. 15 U.S.C. §2613.

Additionally, EPA's Chemical Data Reporting rule allows claims of confidentiality for chemical identity, site identity, and processing and use information. 40 CFR Part 2 and 40 CFR 711.30. CBI protection under the CDR rule is limited to data elements where their release would likely cause substantial harm to the business's competitive position.

### **C. CBI Protection for chemical ingredients in tires**

The proposed rule incorporates by reference the definition of "trade secret" in the Uniform Trade Secrets Act. Civil Code Section 3426.1(d). This definition requires that a person asserting a trade secret claim demonstrate that the information sought to be protected has economic value and that reasonable efforts have been made to maintain its confidentiality.

RMA members have a property interest in the ingredients in their tires. Ingredients in tire formulations have a recognized economic value. Tire manufacturers spend significant resources developing new tire formulations to improve performance characteristics. Tires differ not because of taste, color or appearance, but because the tire industry is always striving to achieve better performance. Protection of confidential business information is important for tire manufacturers because they are always trying to gain an advantage over their competitors. All RMA members exercise practices to ensure tire formulations are kept confidential and not revealed to the public, and therefore competitors. Public disclosure of chemical identities will make the results of these investments in tire performance available to other companies who will not have to make similar investments.

RMA recommends that DTSC include in the final SCP rule categorical CBI protection for those chemical ingredients in tires that are trade secrets. For example, under the proposed rule responsible entities are required to include in the AA reports information on the "component(s) and/or homogeneous material(s) and its/their associated component(s) that is/are the focus of the AA," and "identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for the product included on the Priority Product list, and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the product." (§69505.5(e)(2)(3)). Rather than asserting a claim of trade secret protection each time tire manufacturers submit an AA report to the Department that includes this information, RMA recommends that DTSC categorically consider this information and all ingredients in tires that are trade secrets to be CBI. Providing categorical exemptions for trade secrets will reduce the burden on industry and the Department to submit and review claims for trade secret protection.

We also recommend that DTSC recognize that the Chemical of Concern in a Priority Product may in and of itself be a trade secret and create a confidential process for Chemicals of Concern in priority products that are considered trade secrets.

**VI. RMA recommends that the definition of Highly Durable Products be modified to include tires**

Section 69503.4 includes provisions for highly durable products, which are defined as products that meet the following criteria: (1) assembled from 100 or more manufactured components; (2) manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five or more years; and (3) the product is typically not consumed, destroyed, or discarded after a single use. (§69503.4(a)(2)(B)(3)). RMA questions DTSC's rationale for including the requirement that highly durable products must be assembled from 100 or more manufactured components. Tires are unlikely to satisfy the first requirement for classification as a highly durable product as they are not manufactured from 100 or more manufactured components. In order to include tires in the definition of highly durable goods, we ask that DTSC reduce or delete the number of manufactured components requirement.

The proposal limits the number of AA's a responsible entity can complete for Chemicals of Concern/ Priority Product combinations for highly durable products. Specifically, the proposal states that for listed highly durable products, "the Department shall specify no more than 10 components and/or homogenous materials per product every 3 years." (§69503.4(a)(2)(B)(2)). In the Initial Statement of Reasons document, DTSC indicates that it limited the number of AA's that must be completed every 3 years to "allow manufacturers of durable products, such as the automobile industry, that have longer product development time frames to conduct the Alternatives Analysis." (Initial Statement of Reasons, R-2011-02, at 101). Further, the Department reasoned that "by limiting the components or homogeneous materials in the components as well as when the specified durable product is subject to an Alternatives Analysis, manufacturers are provided adequate time to address the durability requirements of the product." Id.

Like automobiles, tires must meet Federal Motor Vehicle Safety Standards (FMVSS). As mentioned previously in these comments, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet FMVSS. Changes in tire composition could affect the stopping distance of tires, tire wear, tire fuel efficiency standards and possibly other safety-related factors. Any change in the composition of tires typically requires feasibility studies and multiple tests to ensure that the tires continue to meet FMVSS. We request that DTSC amend the definition of highly durable products to allow tires to be classified as highly durable products in order to provide the tire manufacturing industry with "adequate time to address the durability requirements of the product." Id.

**VII. RMA recommends that DTSC include a workable definition of the Alternatives Analysis Threshold Exemption that is based on actual exposure and risk**

Section 69503.5 stipulates that "the Department shall specify an alternative analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product." (§69503.5(c)). Past drafts of the Safer Consumer Product rule included a *de minimis* exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1%

for all other chemicals. We recommend that DTSC include an Alternatives Analysis Threshold Exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1% for all other chemicals and provide DTSC the discretion to set lower or higher Alternative Analysis Threshold Exemptions as needed.

RMA recommends that the final rule acknowledge that all chemicals do not pose the same risk. Failure to include a default Alternatives Analysis Threshold Exemption or a screen that will allow DTSC to focus on Priority Products that pose the greatest risk, will slow down the risk reduction process which is envisioned by the statute (AB1879). We strongly urge DTSC to include a default Alternatives Analysis Threshold Exemption in the final rule.

### **VIII. Alternatives Analysis Report**

#### **A. RMA supports the requirement in the first stage of the Alternatives Analysis to identify the function, performance, and legal requirements associated with the Priority Products that must be met by the alternatives considered.**

In the first stage of the AA, “the responsible entity shall identify the function, performance, and legal requirements associated with the Priority Product that must be met by the alternatives being considered.” (§69505.3(b)(1)). In previous comments filed on past drafts of the Safer Consumer Products regulation, RMA expressed concern that prior drafts failed to adequately take into account differences between chemicals that are added for style, attractiveness or other nonessential purposes, and chemicals that are included in complex mixtures (such as tires) and whose presence in the product is necessary to impart an essential function (such as stopping distance, tire wear, and fuel economy of the tire). RMA strongly supports the inclusion of this provision that requires responsible entities to identify the function of the CoC in meeting the Priority Product’s function in determining whether an alternative chemical is feasible.

#### **B. RMA does not support the possible requirement to conduct research and development projects or fund a green chemistry challenge grant for priority products where no alternative chemical is selected because it is essentially a tax on manufacturers.**

After completing the first stage of the AA, if a responsible entity determines there is no functionally acceptable alternative chemical, the responsible entity may submit an abridged AA. (§69505.2(b)). However, even if the entity demonstrates that no viable alternative chemical currently exists, it may be required to conduct a research and development project or fund a green chemistry challenge grant for the product. (§69506.9). This essentially “taxes” a manufacturer even when there is a no substitute for the Chemical of Concern.

Section 69506.9 specifies that the requirement to initiate a research and development project or fund a challenge grant is to: “(a) Design a safer alternative to the Priority Product; (b) Improve the performance of a safer alternative to the Priority Product; (c) Decrease the cost of the safer alternative to the Priority Product; and/or (d) Increase the market penetration of a safer alternative to the Priority Product.” *Id.* This raises significant confidentiality issues in an

industry (such as the tire industry) where the products have important and significant chemistry-based differences. Developing a one-size-fits-all substitute would be unworkable for RMA members.

**IX. DTSC should substantiate the need for information required to be submitted under the proposed rule**

Responsible entities are required to submit a vast amount of information in Preliminary and Final AA Reports. (§69505.5). For example, responsible entities are required to submit information on “the proximity of the place(s) of product manufacture to one or more source(s) of virgin or recycled materials that directly or indirectly influences the type and/or amount of Chemicals(s) of Concern in the Priority Product.” (§69505.5(d)(5)). DTSC has not substantiated the need for information pertaining to a manufacturer’s proximity to recycled materials that influence the type and/or amount of a CoC in the Priority Product. Reporting requirements under the proposed rule will require significant resources and time from DTSC and the companies that submit the data. RMA recommends that the reporting burdens under the proposal be justified by a specific and clearly demonstrated need for the information.

**X. DTSC should not determine whether safer alternatives exist for the chemical ingredients in tires**

As part of the Alternatives Analysis, a responsible entity shall include retaining the Chemical of Concern in the Priority Product as one of the alternatives being considered. (§69505.4(a)(1)(B)). However, despite the determination that a technically and economically feasible alternative chemical does not exist, DTSC may determine and notify a responsible entity that it believes there is an alternative chemical that is “safer”. (§69506.6(b)). Responsible entities that receive this notification shall cease to place the product into the stream of commerce in California within one year. DTSC can also ban the product from being sold in California.

DTSC should not specify which chemical ingredients should be used in tires. All RMA member make tires that are safe. As discussed above, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet National Highway Traffic Safety Administration Federal Motor Vehicle Safety Standards. Should DTSC require tire manufacturers to use an alternative chemical that the industry has determined through an Alternatives Analysis is not technically or economically feasible, the tire manufacturing industry will be unable to comply with the proposed regulation and federal law at the same time. RMA recommends that where safety and performance of a consumer product are regulated by other Federal or State agencies, DTSC should not be empowered to determine and/or require that a safer alternative chemical should be used in the Priority Product.

**XI. RMA recommends that DTSC not expand the end-of-life management requirements**

Section 69506.8 specifies that end-of-life management is required for Priority Products for “which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life.” Tires are not managed as hazardous waste in California, so assuming tires are

selected as a Priority Product, an end-of-life management program should not be required for tires.

RMA and its members have engaged in a sustainable end-of-life management program for tires without the necessity of regulation. For more than two decades, the tire manufacturing industry has developed a voluntary post-consumer product recycling program that has resulted in approximately 90% of its product being recycled.<sup>1</sup> RMA does not support mandatory end-of-life management requirements for tires. Any end-of-life management requirements for tires will disrupt the established, voluntary, scrap tire market.

**XII. RMA supports the inclusion of the Safer Consumer Products Partner Recognition List**

The Safer Consumer Products Partner Recognition List may enable DTSC to fulfill the intent of the statute in a more appropriate manner by eliminating the need to focus time and resources on products that pose no risk. Section 69501.4(d) specifies that persons may voluntarily complete an AA on a consumer product that has not been listed as a Priority Product, and/or voluntarily provide information that is helpful to the Department in implementing this chapter. Further, the Department shall maintain on its website a SCP Partner Recognition List that identifies persons who have voluntarily provided information to DTSC that advances the quest for safer consumer products.

While RMA supports the inclusion of the opportunity to submit an AA to DTSC before a product is listed as a Priority Product, we question what specific information would be most helpful to the Department in advancing the “quest for safer consumer products”. Additionally, we ask that the Department specify that manufacturers can be placed on the Safer Consumer Products Partner Recognition List even when an AA report specifies that no economically or technically feasible alternative exists.

**XIII. RMA believes that responsible entities should not face penalties of perjury for errors made on information submitted to DTSC**

Section 69501.3(c) specifies that all information submitted to DTSC by a responsible entity is submitted under penalty of perjury. Specifically the proposed rule requires a company officer or owner to certify as follows: “under penalty of perjury... this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that submitting false information or statements is a punishable offense.” Id. Nothing in the statute confers authority on DTSC to require that an owner or an officer of a company must certify under penalty of perjury that the substantiating information is correct. This requirement results in the

---

<sup>1</sup> See RMA Scrap Tire Markets Internet page, available at <[http://www.rma.org/scrap\\_tires/scrap\\_tire\\_markets](http://www.rma.org/scrap_tires/scrap_tire_markets)> and RMA, Scrap Tire Markets in the United States 9th Biennial Report (May 2009), available at <<http://www.rma.org/getfile.cfm?ID=985&type=publication>>.

potential imposition of a criminal penalty if a question is raised about the accuracy of the information. DTSC lacks the authority to create circumstances that give rise to a criminal penalty; only the California Legislature has this authority.

RMA recommends that DTSC require responsible entities to certify that the submitted information has been completed in compliance with the requirements of this rule and that confidentiality claims are true and correct. EPA uses this certification language in the TSCA Inventory Update Reporting Modifications; Chemical Data Reporting final rule (CDR final rule). 76 Fed. Reg. at 50816. Specifically the CDR final rule specifies that “the authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person’s name, official title, and e-mail address.” *Id.* at 50872.

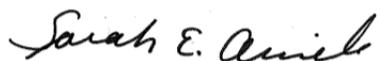
#### **XIV. Conclusion**

The tire industry supports sustainable production and the development of methods to reduce the risks of exposure to chemicals used in products. However, the proposed regulation grants virtually unreviewable authority to DTSC to require substitution of chemicals in tires. This threatens tire manufacturers ability to meet and comply with Federal Motor Vehicle Safety Standards and the requirements of the July 2012 proposed Safer Consumer Products regulation.

As written, the informal draft regulation cannot be applied to tires in any feasible way. RMA recommends that DTSC revise the regulation to: (1) ensure that DTSC responds to petitions to delist a Priority Product before a responsible entity must complete an Alternatives Analysis; (2) harmonize the proposed regulation to enable tire manufacturers to comply with both Federal Motor Vehicle Safety Standards and the proposed regulation; (3) provide a process that enables tire manufacturers to demonstrate the need for additional time to complete the Alternatives Analysis process in order to conduct feasibility, safety, and performance testing on alternatives; and (4) provide a categorical CBI exemption for ingredients in tires.

RMA again thanks the California Department of Toxic Substances Control for this opportunity to comment on the informal draft regulation. Please contact me at (202) 682-4836 if you have questions or require additional information.

Respectfully Submitted,



Sarah E. Amick  
Environmental Counsel  
Rubber Manufacturers Association



## San Benito County Integrated Waste Management Department / Regional Agency

3220 Southside Road • Hollister CA 95023 • (831) 636-4110 • Fax (831) 630-5164 • [mrose@cosb.us](mailto:mrose@cosb.us)

Normandy A. Rose, Director  
Lisa Jensen, Recycling & Resource Recovery Coordinator

October 11, 2012

Debbie Rafael, Director  
DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806  
Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

### RE: Comments on Draft Regulations for Safer Consumer Product Alternatives

Dear Director Raphael:

The San Benito County Integrated Waste Management Regional Agency has long been a supporter of the development of the Green Chemistry program in California. As a local government agency we have anxiously awaited the implementation of this program as we recognize the multi-disciplinary benefits that it will provide: elimination of pollutants at the source thereby removing the need for costly pre-treatment to the POTW and fewer materials to handle through Small Quantity Generator (SGQ) and Household Hazardous Waste (HHW) programs. These actions ultimately reduce costs for both the recipient business and generating industry, as well as local government HHW programs.

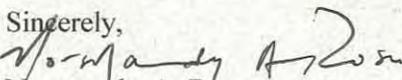
It is unfortunate that many of the manufacturers of these targeted materials provide non-toxic products to our European Union neighbors but balk at providing the same courtesy to the United States in general and California in particular. It is equally unfortunate that product packaging continues and has expanded to include hazardous constituents.

We would like to go on record as stating that we generally support the proposed regulation but would respectfully request that you consider two significant revisions that have been vetted by the California Product Stewardship Council (CPSC) of which we are a member:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We know you recognize that it past time for California to act on implementing a Green Chemistry program. We have a unique opportunity to become a world leader in creating producer responsibility systems that drive and incentivize green/cradle to cradle design. California needs to return to its rightful of leadership in the field of sustainability.

Sincerely,

  
Normandy A. Rose  
Director

COUNTY OF SANTA BARBARA  
PUBLIC WORKS DEPARTMENT  
123 East Anapamu Street  
Santa Barbara, CA 93101  
805\568-3000 FAX 805\568-3019



SCOTT D. MCGOLPIN  
Director

October 10, 2012

California Department of Toxic Substances Control  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806  
Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**RE: Comments on Draft Regulations for Safer Consumer Products**

Dear Director Raphael:

The County of Santa Barbara strongly supports the development of a Green Chemistry program in California to identify "Chemicals of Concern" and reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year, and local government household hazardous waste (HHW) collection programs bear the burden of managing them at a substantial cost. As such, we are very supportive of California's Safer Consumer Products Program that will promote the re-design of these problem products.

While we generally support DTSC's proposed regulations, we request that you consider the following modifications:

(1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website, and DTSC should invite input from local government agencies and the public prior to approving the plans.

(2) Municipality costs – DTSC should add "cost to municipalities" as a prioritization factor in determining which chemicals will first undergo an alternatives analysis. By removing problem chemicals from products, HHW programs will have fewer products to manage, resulting in significant cost savings to taxpayers and ratepayers. Statewide, these cost savings could equal tens of millions of dollars.

We look forward to DTSC's continued leadership in making California a world leader in producer responsibility systems that drive green design and reduce the use of hazardous materials.

Sincerely,

Mark Schleich  
Deputy Director, Public Works Department

AA/EEO Employer

Thomas D. Fayram, Deputy Director

Dacé B. Morgan, Deputy Director

Mark A. Schleich, Deputy Director

Mark Paul, Chief Financial Officer

Michael B. Emmons, County Surveyor

[www.publicworkssb.org](http://www.publicworkssb.org)

## GCREgs@DTSC

---

**From:** Keemo Jeong <keemo77@naver.com>  
**Sent:** Thursday, October 11, 2012 8:32 AM  
**To:** GCREgs@DTSC  
**Cc:** Madriago, Odette@DTSC; Wong, Jeff@DTSC; youngil2.kim@skhynix.com; seungjong.ko@skhynix.com; keemo.jeong@skhynix.com; steve@ksia.or.kr  
**Subject:** Comments of the SIA in Korea on Proposed Safer Consumer Products Regulations, California Regulatory

Dear Ms. Von Burg:

On behalf of the Semiconductor Industry Association of Korea(KSIA), we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxics Substances Control (DTSC), published in the California Regulatory Notice Register (file number Z-2012-0717-04) on July 27, 2012.

SIA in Korea is the trade association of the semiconductor industry in Korea. More information about our organization can be found at <https://www.ksia.or.kr/renewal/eng/>.

We are writing in support of the comments filed on October 11, 2012 by several technology associations based in the United States. The organizations are the Information Technology Industry Council (ITIC), TechAmerica, the Consumer Electronics Association (CEA), and the Semiconductor Industry Association (SIA) in the United States. The members of SIA in Korea have reviewed the comments of these other technology associations and we endorse these comments. As discussed in detail in those comments, we believe that these proposed regulations set forth a burdensome and subjective regulatory scheme that will be infeasible and expensive for manufactured products such as semiconductors. In addition, we believe that some requirements may represent a technical barrier to trade (TBT) under the rules of the World Trade Organization (WTO), and could result in the disclosure of trade secrets and confidential business information (CBI).

We appreciate the opportunity to provide input on these proposed regulations.

Sincerely,  
Keemo Jeong

\*\*\*\*\*

SK Hynix, ESH R&D Centre

Keemo Jeong  
Mobile : +82-10-2274-8217  
Phone : +82-31-639-6296  
E-mail : [keemo.jeong@skhynix.com](mailto:keemo.jeong@skhynix.com)  
\*\*\*\*\*

This information contained in this message may be confidential and legally privileged. If you are not the intended recipient, you are hereby notified that any use, dissemination or reproduction of the contents of this message is strictly prohibited and may be unlawful. If you are not the intended recipient, please contact the sender by return e-mail and

destroy all copies of the original message.

---



October 11, 2012

Debbie Raphael  
Director, Dept. of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Products Draft Regulations**

Dear Director Raphael:

Sierra Club California strongly supports the Department of Toxic Substances Control (DTSC) proposed regulations on Safer Consumer Products (SCP) and urges its swift adoption. California needs protection from dangerous exposure to toxic chemicals in products and must not delay such important environmental and public health safeguards. We appreciate the time, efforts and careful consideration that you and your staff have put into drafting the regulation.

There are more than 100,000 chemicals currently in commerce and more than 2,000 new chemicals are added each year. Existing laws do not adequately protect the environment and consumers from unnecessary exposure to toxic levels of these chemicals. According to the Berkeley Center for Green Chemistry, health care costs for California's children and workers from chemical and pollution-related diseases exceed \$2 billion per year. Preventable chronic illnesses, developmental and behavioral disorders such as ADHD, infertility, cancer and birth defects are linked to exposure to harmful toxins in products. The harm does not just end with consumers. Dangerous substances from products will make their way to the environment where they pollute our water and harm wildlife. Local governments are usually tasked with water treatment and cleanup efforts that costs taxpayers billions of dollars each year.

Sierra Club California strongly supported the 2008 enabling legislation that required the SCP regulation. The legislation aimed to address single-chemical ban proposals at the legislature and received support and collaboration from environmental groups, public health advocates, and the chemical industry. When it was enacted, we were confident that our collaboration would result in smart rules and that the industry would continue to support the effort. Since then, there have been delays and industry efforts to weaken the law. Finally, after four years of regulatory process, we are about to see the bill implemented through the new SCP regulations. We anticipate that there will be no further delays that would require us to seek further legislative action to ensure that consumers and the environment are protected from toxics in products.

We commend DTSC staff for the many positive aspects in the latest iteration of the regulations and support the department's plan to move forward with implementation. The regulations are scientifically sound and are consistent with the feedback from that DTSC has received from its science panel.

Below is a list of positive highlights and suggested amendments to strengthen the regulation.

**Sierra Club California strongly supports the following elements in the regulation:**

1. A comprehensive list of Chemicals of Concern (COC). The regulation currently includes a list of 1300 COCs drawn from existing lists prepared by respected government, scientific and regulatory bodies that identify chemicals that are known to be harmful. The list provides the necessary signal to the market that the state expects stewardship for hazardous chemicals. A comprehensive list will also help avoid regrettable substitutions. However, for the list to be most effective, it must also include chemicals hazardous to the environment in addition to those posing public health threats.
2. There is noteworthy effort in capturing environmental endpoints and impacts. We appreciate the focus on the natural environment in the definitions of environmental impact. Capturing environmental endpoints such as wildlife, wetlands, and watersheds or larger ecosystems will ensure that we address products that contain chemicals harmful to the natural environment.
3. End-of-life Product Management. The automatic requirements for end-of-life management are crucial to ensure proper handling of priority products at the end of their useful life. These requirements will also encourage manufacturers to incorporate innovation into their designs to create greener products.
4. Regulatory Response Selection Principles. By including the "Regulatory Response Selection Principles" in the regulatory response process, the Department can support innovation and alternatives that promote protection for the environment and human health. We strongly support criteria that emphasize alternatives that will achieve the best results in limiting impact, exposure and pollution and do so in a timely manner.
5. Assessor Certification. The proposed third-party assessor certification program will help ensure quality information received from manufacturers and responsible parties. This will also enhance the likelihood of acceptable and unbiased alternative assessments.

Sierra Club California urges that the following amendments be made to improve the proposed regulation.

1. Increase the number of products addressed within the first three years of implementation (§ 69503.4). Implementation of the regulations should be robust to meet expectations established by the enabling legislation, retain public support, and protect the environment and public health. The current plan to address no more

than five priority products during the initial phase of implementation suggests this is a pilot program, rather than the protective program the legislature intended. A ramp up during the first year of implementation could be reasonably expected, but after that first year, the program should be fully implemented and address more products. We urge DTSC to revisit its plan for implementation to help avoid the need for additional legislative action.

2. Improve the public involvement process. The implementation process should be transparent, and offer more information and opportunities for the public to provide comments before key decisions are made. Below are some specific suggestions:
  - a) Public input should be solicited prior to initial release of Priority Product List and Work Plan. The Department should also seek comments on the Alternative Assessment (AA) Work Plans in parallel with DTSC review. Comment periods should be 45 days minimum.
  - b) In the list of documents that DTSC will make available online, all public comments should be included. § 69501.5 should be modified to include public comments on work plans (referenced on page 39, line 2 to 3).
  - c) Additionally, the Department should revise the wording in § 69505.5, page 47 line 14, from “presented in matrix” to “*summarized* in matrix”. In its present form, a matrix will not provide enough information to the public and stakeholders therefore should only be used as a way to summarize key points and additional information to be linked.
3. Problematic omission of the Water Board/EPA 303(d) list from the List of Lists (§ 69502.2). The list of chemicals of concern does not include the most common environmental contaminants that pollute our water and harm habitat. By adding the 303(d) list, DTSC will ensure the regulations capture those pollutants. The Water Board/EPA 303(d) list is the list of “impaired” water bodies and the chemicals impairing them in the state of California. It is congruent with the Department’s Statutory Intent and Requirement as it is reliable and readily available information that is scientifically sound. Even though the list appears under the definition of “adverse water quality impacts”, it also needs to be added to the List of Lists and the chemicals to the list of COC.
4. Remove incentives to hide data (§ 69503.2). Prioritizing products based on availability of information will incentivize the practice of hiding data and discourage manufacturers and responsible parties from publishing scientific studies on chemicals.
5. Exposure pathways must be identified in the Preliminary Alternative Assessment Report (§ 69505.5). A major reason consumer products pollute the environment is that manufacturers are unaware of environmental exposure pathways. DTSC should require the elements of § 69505.5(g) to be included in the Preliminary AA report work plan.

6. Need to increase the number of components in highly durable products regulated every three years (§ 69503.4). As currently written, DTSC will only focus on 10 components in each manufactured product that is considered highly durable every three years. This set maximum will further delay implementation and weaken the program. A durable product, as noted in the regulation, could contain 100 or more components and each of those components can represent a pollution source. Some products may have thousands of components and by addressing only 10 components every three years, it will take decades for safer alternatives to appear on the market. We recommend that DTSC set a maximum percentage of components in each manufactured product that can be regulated every three years as a compromise that will protect manufacturers, consumers and the environment.
7. Timeline should be tightened to reduce the amount of time from now until safer products are on shelves (§ 69503.4). The level of flexibility in § 69503.4 might result in delays. Preliminary AA Reports should not be submitted more than 180 days after a product is listed as a Priority Product except in very rare circumstances. Safer products need to be available to consumers soon and not years from now. We recommend that DTSC establish narrow criteria for allowing extensions of the timeframes specified in the regulations under exceptional circumstances.
8. More consideration needed for environmental impact and costs to other agencies, organizations and companies in the Regulatory Response Selection Principles (§ 69506).
  - a) When identifying administrative and other costs associated with safer consumer products, DTSC should also take into consideration the burden placed on other government agencies and organizations such as the Department of Parks and Recreation, the Department of Fish and Game, non-profit land stewardship organizations, and companies that manage wastes. On page 52 lines 22 to 23 should include “*other government agencies, non-profit organizations, other private businesses*”.
  - b) In addition, the negative impacts to the natural environment should be considered throughout the regulation and especially as part of the Regulatory Response Selection Principles. The principles were set up to provide guidelines on how DTSC will select regulatory responses therefore it would be important for the Department to stress environmental impact as part of the list of principles. On page 52 lines 24 to 25, the wording should be modified to read “upon sensitive subpopulations *and ecosystems*”.
9. The Regulatory Response Selection Principles (§ 69506) should specify that the Department will seek timely protection for human health and the environment. As mentioned in our previous points, timeline is a concern for Sierra Club California. We would like to see safer consumer products be placed in commerce as soon as possible before worse pollution and more illnesses occur. This sentiment needs to be conveyed in § 69506 as one of the main guiding principles for selecting regulatory responses.

10. End-of-life management plan needs input prior to approval (§ 69506.8). We urge that DTSC solicit public comments on proposed product stewardship plans to ensure transparency and effective waste management from manufacturers. This should be done prior to approving the plan and all information should be posted online and available to the public.
  
11. Remove exemptions for “historic products” (§ 69501.1). According to the Initial Statement of Reason, DTSC clarified that “historic products” will be exempted from the regulations because even though they still exist, they are no longer in production. This blanket exemption should not be made without further evaluation on public and environmental health threats from the product, part of the product and its components. The Department should strike this definition out of the regulation and make these considerations when developing product-specific regulatory responses, using the established principles.

Thank you for the opportunity to provide these comments. We strongly support the regulations and feel that they will move us in the right path to safer consumer products.

Sincerely,

A handwritten signature in black ink, appearing to read "Annie Pham", with a long horizontal flourish extending to the right.

Annie Pham  
Policy Advocate

## GCREgs@DTSC

---

**From:** Margaret Sjostrand <marstrand2000@yahoo.com>  
**Sent:** Thursday, October 04, 2012 8:11 PM  
**To:** GCREgs@DTSC  
**Subject:** Protect consumers

This is to urge California legislators to act to protect consumers from dangerous chemicals in the products we buy. This is a moral decision which is essential for the health of all Americans. It is inconceivable to me that our elected officials would even hesitate to establish the strongest of rules necessary to accomplish safety for all. There are already too many toxic chemicals in our environment. Remember, constituents will be watching!

Thank you,

Margaret Sjostrand

## GCREgs@DTSC

---

**From:** Andrea Snow <ajsnow@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 11:14 AM  
**To:** GCREgs@DTSC  
**Subject:** regulations

**Categories:** Comment

If I understand it, regulations protecting consumers from dangerous chemicals were supposed to be strengthened by January 2011. It's taken this long for our legislators to come up with an agreement -- FINALLY -- but one that is now threatened by the powerful chemical industry. Don't let the chemical industry derail public health. The DTSC must finish writing regulations and enact them!

Thank you,  
Andrea Snow



October 11, 2012

**BY E-MAIL (gcregs@dtsc.ca.gov) & U.S. Mail**

Kryisia Von Burg  
Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, California 95812-0806

Re: Comments on Draft Regulations (Released July 27, 2012)

Dear Ms. Von Burg:

On behalf of one of our clients, this letter provides comments on the draft regulations ("Proposed Regulations") known as the Safer Consumer Products regulations (proposed 22 CCR §§ 69501 - 69511). The comments are ordered according to section.

*The Regulations Should Respect the Statutory Limitation of  
Consumer Products and Should Not Cover All Products.*

As written, the proposed regulations make every product a consumer product. This is an improper and unauthorized extension of the enabling legislation. This improper extension of the law to include products other than consumer products is the result of "person" being defined to extend beyond natural persons. Person should be defined as natural persons; it should not include corporations and other entities.

In November 2010 and December 2011, we submitted comments to the then proposed regulations requesting that the Department narrow the definition of "person" because it was overbroad and inconsistent with the enabling legislation. However, the definition of "person" remains the same in the Proposed Regulations as it did in 2010. Namely, proposed section 69501.1(a)(44) defines "person" by incorporating Health and Safety Code section 25118. Section 25118 defines person to mean not only an individual, but also a "trust, firm, joint stock company, association, and corporation, including . . . the state . . . and the federal government or any department thereof."

There are at least three reasons why the state should revise the draft regulations to define "person" in the Proposed Regulations as an individual rather than the vastly broader definition presently offered. First, the word "person" should be interpreted in context, not in isolation, according to standard California rules of statutory interpretation. The context of "person" as a user of a "consumer product" in Health & Safety Code section 25251(e) strongly favors defining person as an individual, not a corporation or the federal government.

Second, the current draft definition would absurdly define anything in the state as a consumer product, and absurd consequences are a strong indicator that language has extended beyond the Legislature's intent. The Department's proposal would make an aircraft carrier (97,000 tons), the Capitol Building, a freight train and an industrial forklift all consumer products. Because the federal government, the State, and companies that operate freight trains and forklifts all are "persons" and "use" large navy ships, the Capitol and freight trains, all of these things would be "consumer products" under the State's proposed definition. This is turning the title of the legislation and the key provision defining its scope completely upside down. Similarly, it is absurd to think of a fork lift as a "consumer product." Consumer products should be defined as things that *people* use when they are acting as consumers, not all things under the sun, and not things that are obviously industrial products.

Third, if the Department's currently proposed definition of person were adopted, it would expand the definition of "consumer product" to mean any product whatsoever, and thus would render the word "consumer" in the statute not only meaningless, but deceptive. Each word in a statute should be given meaning and the Initial Statement of Reasons fails to explain how the Department has given meaning to the word "consumer" in this statute.

The Initial Statement of Reasons ("ISR") explains the Department's choice of an expansive definition of "person" as follows: "This definition is consistent with other uses in programs administered by DTSC." (ISR at 31). No such program is identified, however, and we are not aware of any other program that DTSC administers relating to consumer products. Indeed, the definition of person that DTSC proposes to incorporate is from the original 1972 California hazardous waste control law that focused on controlling the generation, handling, storage, transport and disposal of hazardous waste -- a very different context from how to define the reach of a "consumer product" law.

#### *Food Packaging Should Be Excluded*

The regulations should expressly exclude food packaging from the green chemistry program. We request that Proposed Regulations section 69501(b) (where the exemptions are now located) be revised to include such an exemption. Alternatively, we request that the Department determine, before the regulations become effective, that FDA's regulation of food packaging materials addresses the matters noted in section 69503.2(a)(3) such that the proposed regulations would not apply to food packaging materials.

#### *Trade Secret Protection*

Overall, the provisions for protecting trade secrets are unreasonably costly to follow and exclude from protection altogether certain currently protected information.

Proposed section 69510(a) only should require that items one through four be specified in the first instance, with a statement that adequate measures to restrict access have been taken (without the need to detail such measures). It is not reasonable to require further substantiation for most of the information that will be submitted to DTSC and in circumstances where no controversy concerning the applicability of the trade secret protection applies. Sections 5 through 10 of proposed section 69510(a) are unduly costly and not necessary in the first instance. In the event of an important controversy, it is possible that the information called for in sections 5 through 10 would be cost justified, but that determination should be made on a case-by-case basis by DTSC. Moreover, fully complying with these provisions likely will

require the generation and sharing with DTSC of further trade secret information and provide undue burden on entities or persons that submit information. Lower cost alternatives should be thoroughly explored for this provision, and have not yet been so explored or detailed in the Initial Statement of Reasons.

The requirement in proposed section 69510(b) of automatically providing a redacted version of a trade secret document is not reasonable or cost justified. The regulations potentially call for substantial document submissions. Redacting substantial submissions can become very expensive very quickly. Again, the need to redact should be identified on a document-specific and context-specific basis where needed, not generally applicable to all documents submitted.

Section 69510(f) should not be adopted. This provision is not authorized by the enacting legislation. The Initial Statement of Reasons claims that section 69510(f) implements section 25257(f) of the Health and Safety Code. This claim, however, is not accurate. Section 25257(f) simply excludes hazardous trait submissions from the specific procedures governing trade secrets found in section 25257, it does not repeal all of the general protections of trade secret law in California as they relate to hazardous trait submissions. Even if section 69510(f) were to be found to be authorized by statute, which we dispute ever could be the case, it is unduly burdensome and a substantially less restrictive alternative should be utilized in order to better protect trade secrets. Since proposed section 69510(f) should not be adopted and is not authorized by the enacting legislation, sections 69510(g) and 69510(h) also should not be adopted.

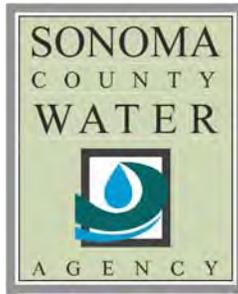
Section 69510.1 should contain a provision allowing for the return of information to the submitter that has been claimed to be trade secret and that the submitter contends is trade secret information if California determines that it cannot agree with the submitter's claim. In order to encourage proper submissions, and in order to allow a company to opt out of sales in California if necessary to protect information recognized as trade secret information outside of California, California should allow for the return of information when California disagrees that a claim of trade secret protection is valid.

Sincerely,



Gary M. Roberts

GMR:ar



October 11, 2012

**VIA ELECTRONIC MAIL**

gcregs@dtsc.ca.gov

Director Debbie Raphael  
California Department of Toxic Substances Control  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806

**SUBJECT: DRAFT REGULATIONS FOR SAFER CONSUMER PRODUCT REGULATIONS**

Dear Director Raphael:

I am writing to indicate our support for implementation of Safer Consumer Product Regulations now under consideration by the Department of Toxic Substances Control and to urge you to consider modifying the proposed regulations in order to:

- (1) Require that proposed stewardship plans be posted on the DTSC website with an opportunity for comment by local government agencies and other parties.
- (2) Consideration of the cost to municipalities as a prioritization factor. Local agencies that manage these contaminants in waste streams and sanitation systems could realize significant future cost savings by reducing the volume of these substances in commerce.

As a wholesale water provider and operator of municipal wastewater treatment systems holding NPDES permits we are well aware of the potential future costs for removal of trace contaminants from water and wastewater. Advancements in analytical technology often lead to new permit requirements that bring ever lower discharge limits and add new compounds to the list of those that must be measured, monitored and removed from water and wastewater streams.

The most cost effective way to remove these substances from source water and from waste water flows is to reduce their introduction in to the environment on the product side. We strongly support your effort to achieve this goal with the proposed regulations.

California has always led the nation in innovative measures that lead to improved public health and environmental protection and the work your department is doing to develop these new regulations will continue and advance that tradition.

Thank you for your work on this and for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Grant Davis". The signature is stylized and cursive.

Grant Davis,  
General Manager

**From:** Steve McDonald <SteveM@sema.org>  
**Sent:** Monday, September 10, 2012 1:18 PM  
**To:** GCREgs@DTSC  
**Subject:** SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2100-02, Office of Administrative Law Notice File Number: Z-2012-0717-04

**Categories:** Comment

September 10, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**RE: SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2100-02, Office of Administrative Law Notice File Number: Z-2012-0717-04**

The Specialty Equipment Market Association (SEMA) is pleased to provide comments relative to the Department of Toxic Substance Control's proposed addition of chapter 55 to division 4.5 of Title 22, California Code of Regulations. This proposal seeks to adopt regulations to establish a process to identify, prioritize and evaluate those chemicals, and their alternatives, in consumer products that may be considered chemicals of concern.

SEMA is a trade association headquartered in Diamond Bar, California and made up of more than 6,500 mostly small businesses in California and around the country that manufacture, rebuild, distribute and retail parts and accessories for motor vehicles. The products manufactured by our member companies include functional, restoration, performance and styling enhancement products for use on passenger cars, trucks and special interest vehicles of the type that could be affected by any regulation pertaining to chemical content of consumer products.

SEMA requests that the agency restore language that was included in a previous version of the draft regulation regarding "historic products." This language, which would exempt certain products from the scope of the regulation, appears below:

**69501. Purpose and Applicability**

*(4) This chapter does not apply to any historic product that is placed into the stream of commerce in California.*

**69501.2 Definitions**

*(41) "Historic product" means a product that is manufactured or produced prior to the date the product is listed as a Priority Product, and its service, replacement and repair parts produced after that date to repair as-built the historic product.*

It is essential that parts for automobiles remain available to California consumers to maintain vehicles and reduce emissions. Although we are very pleased that historic products and existing inventories of spare parts will be exempted from the regulation, we strongly believe that spare parts produced after that date to maintain and/or repair the historic product as-built should also be treated in this way.

Redesign of spare parts may be technically or economically infeasible due to declining production, economies of scale, consumer expectations and technical design that will render their redesign infeasible, or legally impossible, to ensure that the historic product as-built can meet safety, durability and emissions testing requirements. Without a historic product exemption, the cost of spare parts would be prohibitive and unacceptable to consumers resulting in vehicles being taken off the market due to non-availability of spare parts, as well as having adverse environmental and equal justice consequences.

SEMA members offer thousands of replacement parts to consumers many of which are reviewed, tested and approved in accordance with the Air Resources Board's Executive Order program. To go back and redesign and validate a post model part for the small volume service demand resulting from a material change would be cost prohibitive. The basic economic business model for spare parts is that manufacturers put a marginal supply of spare parts in stock during the production time of a running series. They do not produce spare parts for the total lifetime of the vehicle due to the high costs of warehousing. Thus, to the extent that customers need spare parts beyond what is initially stocked, there is a reproduction-on-demand market whereby suppliers use the "original" tools, materials, production processes and engineering specifications to continue to ensure that vehicles already purchased by consumers can continue to be maintained and in service, as consumers bring their cars in for repair.

If the current service parts supply market is no longer available due to a need to comply with these regulations, the spare parts will need to be redeveloped and sold at much higher costs. The development of a new spare part will involve development of alternative/substitute materials, design/engineering changes, new suppliers, new releases, new durability tests, new system Type Approval (TA), part number changes and far higher costs due to all these factors and declining volumes needed. It is not only impractical, but may be impossible in many instances. If the material formulation changes for a spare part after the end of production of the vehicle, then it will be necessary to ensure that we are delivering components that were tested to comply with federal safety or emissions standards. When production of a vehicle has ceased, such testing is unwarranted.

Again, redesigning motor vehicle parts would result in little benefit while the amount of effort involved makes it infeasible, impractical and in most cases impossible. California parts manufacturers and retailers can ill afford another burdensome regulatory requirement in an economy where sales and profit margins are already minimal.

Thank you for your consideration. We are available to answer any questions you may have.

Steve McDonald  
SEMA Vice President, Government Affairs

---

**San Francisco Bay Regional Water Quality Control Board**

October 10, 2012

Department of Toxic Substances Control  
Attention: Krysia Von Burg, Regulations Coordinator  
P.O. Box 806  
Sacramento, CA 95812-0806  
[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Subject: Proposed Safer Consumer Products Regulations  
(Dept. Reference No. R-2011-02, File No. Z-2012-0717-04)

Dear Ms. Von Burg:

On behalf of the State Water Resources Control Board (State Water Board) and the Regional Water Quality Control Boards (Regional Water Boards), we are submitting these comments on the Department's proposed Safer Consumer Products regulations. We generally support the most recent proposal and wholly support the overarching goals of the regulations, which aim to identify and prioritize chemicals of concern and promote safer alternatives.

The State Water Board and nine Regional Water Boards are responsible for maintaining water quality in State waters to protect beneficial uses of surface and ground waters. As a result of discharges of chemicals available through ordinary commerce, we have found many water bodies in the State to be impaired pursuant to Clean Water Act section 303(d). The Clean Water Act requires us to prepare resource-intensive plans to restore the beneficial uses of these waters, and programs to implement these plans are extremely expensive, both for us and for the regulated community. For many pollutants of concern, end-of-pipe treatment of wastewater and stormwater is not only prohibitively expensive, but technologically infeasible.

The proposed Safer Consumer Products regulations have great potential to reduce public and environmental exposure to harmful and unnecessary chemicals. As explained below, we believe the regulations could go further in addressing water quality concerns.

### **1. Clean Water Act Section 303(d)**

The "303(d) List" should be added to the Safer Consumer Products regulations. Federal Clean Water Act section 303(d) requires that the Water Boards assess water quality data for California's waters every two years to determine if they contain pollutants in excess of water quality standards. The resulting list is based on actual water quality data and sets forth California's highest water quality priorities. The list is consistent with the Chemical List Criteria of the Safer Consumer Products Initial Statement of Reason (pg. 60, Initial Statement of Reason).

**Recommendation:** Add the “303(d) List” to the regulations under section 69502.2(a), Chemicals of Concern Identification (pg. 21, line 21).

## 2. Emerging Concerns

In previous comments dated March 14, 2012, the State Water Board suggested adding the publicly reviewed Chemicals of Emerging Concern list generated by a scientific panel in accordance with the State Water Board’s Recycled Water Policy.<sup>1</sup> We reiterate that comment and further suggest adding the Chemicals of Emerging Concern list generated by a second scientific panel for freshwater, coastal, and marine ecosystems.<sup>2</sup> If not sufficiently controlled, chemicals of emerging concern may become major drivers of future water quality impairment. The Safer Consumer Products regulations should anticipate and prevent future water quality problems. These Chemicals of Emerging Concern lists are consistent with the Chemical List Criteria of the Safer Consumer Products Initial Statement of Reason (pg. 60, Initial Statement of Reason).

**Recommendation:** Add the Chemicals of Emerging Concern lists generated for the State Recycled Water Policy and for freshwater, coastal, and marine ecosystems to the regulations under section 69502.2(a), Chemicals of Concern Identification (pg. 21, line 21).

## 3. Alternatives Analysis Threshold Exemptions

We support the Department’s approach to the exemption in section 69503.5(c), Alternatives Analysis Threshold Exemption (pg. 31, line 29). The proposed threshold is based on a chemical concentration by weight to be specified for each priority product, and not a scientifically baseless one-size-fits-all percentage. Different pollutants and different products have different potencies. The case-by-case language allows for variations in product usage and environmental sensitivities.

## 4. Initial Priority Products

Please modify the regulations to better address non-human environmental pollution, including serious water quality concerns. As currently drafted, the proposed regulations postpone consideration of some of the highest priority water quality problems in the State (e.g., copper, nickel, phosphates, nitrates, selenium, boron). For the first few years, chemicals selected as initial priorities must meet both human health and environmental criteria. This approach excludes many water pollutants because, although they may pose significant water quality threats, they often pose few human health risks. Selecting one of the five initial priority products to address a purely water quality threat would better illustrate the applicability and benefits of these regulations.

As currently written, the proposed regulations identify two groups of Chemicals of Concern. The first group includes chemicals exhibiting one or more hazard traits (i.e., carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, or bioaccumulative toxicity); the second group includes chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. The 303(d) list and Contaminant of Emerging

---

<sup>1</sup> [ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/CECpanel/CECMonitoringInCARecycledWater\\_FinalReport.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/CECpanel/CECMonitoringInCARecycledWater_FinalReport.pdf)

<sup>2</sup> [ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/692\\_CECecosystemsPanelReport\\_Final.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/692_CECecosystemsPanelReport_Final.pdf)

Concern lists could conceivably be added to either group, under section 69502.2(a)(1) or section 69502.2(a)(2), Chemicals of Concern Identification (pg. 21, line 24, and pg. 22, line 24), because the chemicals on these lists are generally toxic, bioaccumulative, or have otherwise demonstrated specific hazard traits in water. Several alternatives strategies exist for the Department to select an initial priority product based solely on its water quality implications.

**Recommendation:** Add the 303(d) list and the Chemicals of Emerging Concern lists generated for the State Water Board's Recycled Water Policy and for freshwater, coastal, and marine ecosystems to section 69502.2(a)(1), Chemicals of Concern Identification (pg. 21, line 24).

**Recommendation:** Alternatively, add these lists to section 69502.2(a)(2), Chemicals of Concern Identification (pg. 22, line 24), and modify section 69503.3(g), Process to Evaluate Products Using the Prioritization Factors (pg. 29, line 5) as shown below:

- (g) Initial Priority Products List(s). Prior to January 1, 2016, the Department may list a product as a Priority Product only if the product is being listed on the basis of one or more Chemical(s) of Concern in the product that meet ~~both~~ two of the following criteria:
- (1) The chemical meets one or more of the criteria specified in subsection (a)(1) of section 69502.2; ~~and~~
  - (2) The chemical meets one or more of the criteria specified in subsection (a)(2) of section 69502.2; ~~or~~
  - (3) The chemical is on the Clean Water Act §303(d) list of impaired water bodies or a Chemicals of Emerging Concern list generated for the State Water Board's Recycled Water Policy and for freshwater, coastal, and marine ecosystems.

## 5. Transparency and Public Involvement

Please strengthen opportunities for transparency and public involvement. We applaud your approach to balancing intellectual property rights with the need to identify chemical product exposure pathways. Lack of access to chemical data, coupled with few mechanisms to remove harmful chemicals from the marketplace, has led to health and environmental harm. Regulatory transparency, including opportunities for public involvement, will be crucial to the success of your program. Innovation thrives when information is clear and available.

Effective pollution problem-solving can be compromised when exposure pathways to surface waters are overlooked. Explicit identification of exposure pathways through a simple conceptual model early in the process, coupled with public participation, could help ensure that all exposure pathways are identified and none are omitted. As written, this information would not be available until the Final Alternative Analysis is completed and public opportunities to influence the process are more limited.

Similarly, public participation in the development of work plans and stewardship plans will ensure that the best ideas are considered and implemented. For example, the California

Department of Resources Recycling and Recovery is inviting public input on its carpet and paint product stewardship plans.

**Recommendation:** Require a simple conceptual model with the Preliminary Alternatives Assessments work plans under section 69505.3, Alternatives Analysis: First Stage (pg. 41, line 10).

**Recommendation:** Include a formal public comment period under section 69505.3, Alternatives Analysis: First Stage (pg. 41, line 10), and for any significant work plan revisions.

**Recommendation:** Invite input from State and local government agencies and the public prior to approving stewardship plans under section 69506.8(a)(2)(A), End-of-Life Management Requirements (pg. 58, line 1).

**Recommendation:** Include the following in section 69501.5, Availability of Information on the Department's Website (pg. 18, line 42):

- All documents related to the three recommendations above.
- All materials cited in section 69505.1(h), Alternative Analysis General Provisions (pg. 39, line 1), and related public comments and correspondence with interested parties.
- Proposed stewardship plans prepared pursuant to section 69506.8(a)(2)(A), End-of-Life Management Requirements (pg. 58, line 1), not only final plans.

## 6. Costs

Please expand the assessment of the economic impact of the proposed regulations. As written, the findings do not assess the financial impacts on communities exposed to unregulated chemicals. Ecological impacts are difficult to anticipate and their costs are difficult to estimate, but the costs are real and significant. When such expenses are borne by government agencies, they are often over-looked. In 2001, U.S. EPA estimated that the average cost to develop solutions for any of the roughly 20,000 impaired water bodies was about \$52,000 (the range was \$26,000 to \$500,000).<sup>3</sup> These figures do not include implementing the solutions, which is far costlier, and costs are rising. The future costs of addressing emerging contaminants could be greater still. Prevention efforts, such as those outlined in the proposed regulations, will be far more cost effective. However, to demonstrate this, the full costs of environmental cleanup efforts must be considered.

**Recommendation:** Consider more deeply the costs associated with mitigating water pollution impacts after they occur under section 69505.4(a)(2)(C), Alternatives Analysis: Second Stage, Economic Impacts (pg. 43, line 28).

**Recommendation:** Address water pollution control costs not only in the Alternative Analysis but also in regulatory decision-making. Add language to section 69503.2, Priority Products Prioritization Factors (pg. 25, line 20), and section 69506(c), Regulatory Response Selection

---

<sup>3</sup> <http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/costfact.cfm>

Principles (p.52, line 15), to consider the costs sustained by government agencies, publicly owned treatment works, non-profit organizations, and private businesses that handle wastes and oversee environmental clean-up efforts.

## 7. Schedule

To make the most of the new regulations, regulatory timeframes should be as short as possible. As written, there is no timeline for the regulatory response process and too much flexibility to extend the process. We hope the Department can avoid drawn-out phase-outs of chemicals contributing to health and environmental harm. The regulations should include specific findings to justify any flexibility provided to extend a schedule.

***Recommendation:*** Make timely action a priority by including a timeline in section 69506, Regulatory Response Selection Principles (pg.52, line 6).

Thank you for this opportunity to offer our input regarding the Safer Consumer Products regulations, and for your hard work and persistence in drafting these regulations. They represent a critical step in chemical policy reform. Because the regulations represent the first comprehensive state effort to find and require safer alternatives, they will likely become a national model. We appreciate your responsiveness to our concerns, and we are confident that the Safer Consumer Products regulations will greatly benefit water quality throughout the State. If you have any questions, please contact Dylan Garner at (510) 622-2116 or by e-mail at [dgarner@waterboards.ca.gov](mailto:dgarner@waterboards.ca.gov).

Sincerely,

Thomas Mumley  
Assistant Executive Officer



October 11, 2012

Via E-Mail [GCRegs@dtsc.ca.gov](mailto:GCRegs@dtsc.ca.gov)

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Subject: Safer Consumer Products Proposed Regulation

Dear Ms. Von Burg:

Stoner Incorporated appreciated the opportunity to meet with the DTSC staff twice on this proposed regulation. For over 70 years, Stoner has been committed to manufacturing and marketing safe and effective products to our customers. We operate two facilities in Lancaster County, Pennsylvania. Stoner Inc. was a 2003 recipient of the Malcolm Baldrige National Quality Award and is committed to continually improving our manufacturing processes and our products to better serve the consumer. Included in these improvements are the protection of human health and the environment. Some of our many, useful products are found in retail stores such as Wal-Mart, Target, and AutoZone. Stoner pursues a mission of helping our customers save time, increase their productivity, and improve the quality of their work.

Stoner Inc. is pleased that the DTSC is focusing on up to Five Priority Products for their initial review. However, without DTSC identifying these products, commenting on the proposed regulation is difficult.

Our primary concerns are the following:

**Chemicals of Concern (COC).**

DTSC should provide a comprehensive list of chemicals of concern, not a list of lists. Stating lists is cumbersome and leads to confusion. Numerous chemicals would be listed two, three, four, and even more times. Providing lists also leaves the opportunity for chemicals to be added or deleted. For this regulation a known set of chemicals should be identified in detail. In addition, the number of COC listed on the lists is unmanageable. The number of COC should be significantly reduced.

**Alternative Analysis Threshold.**

DTSC needs to clearly articulate a number for this threshold. Providing a chemical-by-chemical Alternative Analysis Threshold is not workable. A known scientific de minimus exemption should be granted. Leaving the threshold number to be determined for each chemical will be extremely time consuming. In addition,



threshold numbers set at extremely low levels will be difficult to monitor and financially burdensome for small companies such as ours.

**Qualifications for Assessors**

The requirements for Alternative Assessment (AA) Assessors are substantial. Small to medium size companies need to be able to use their in-house technical staff. As a Ph.D. Chemist for Stoner Inc., my experience and overall knowledge of Stoner Inc.'s products make me the best entity to perform the AA on these products. The current requirements and timelines would be extremely difficult for a small company such as ours to meet. These requirements should provide companies such as ours with alternative requirements to utilize current staff.

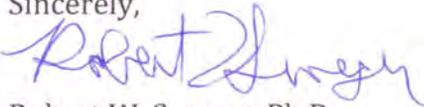
**Confidential Business Information**

Formulas for small companies such as Stoner Inc. are the life-blood of the company. The formulas need to be guarded from competitors since it is this confidential business information that allows us to remain in business. The regulation does not provide for this protection. Thus, the regulation needs to guarantee that such data will be kept confidential.

In summary our major concerns are lack of clear description of chemicals of concern, lack of a harmonized de minimus threshold, excessive requirements for Alternative Assessment Assessors and inadequate protection of confidential business information.

Stoner appreciates your consideration for our concerns. Feel free to contact me at

Sincerely,



Robert W. Sweger, Ph.D.

CC: Odette Madriago, DTSC  
Debbie Raphael, DTSC  
Gareth Elliott, Office of the Governor  
Matthew Rodriguez, California Environmental Protection Agency  
Kristin Stauffacher, California Environmental Protection Agency  
Laurie Nelson, Randlett/Nelson/Madden  
Doug Raymond, Raymond Regulatory Resources (3R), LLC  
Harry Zechman, Stoner Incorporated

## GCREgs@DTSC

---

**From:** TSIA-Celia Shih <celia@itri.org.tw>  
**Sent:** Thursday, October 11, 2012 2:22 AM  
**To:** GCREgs@DTSC  
**Cc:** Madriago, Odette@DTSC; Wong, Jeff@DTSC; tywu@tsia.org.tw; fmhsua@tsmc.com; H\_R\_Lai@umc.com; joey@ITRI.ORG.TW  
**Subject:** TSIA comments on proposed SCP regulations, California Regulatory Notice Register (Z-2012-0717-04) published on July 27, 2012  
**Attachments:** draft ICT industry comments on proposed SCP regulations\_oct 10.pdf  
**Importance:** High

Dear Ms. Von Burg:

On behalf of the Taiwan Semiconductor Industry Association (TSIA), we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxic Substances Control (DTSC), published in the California Regulatory Notice Register (file number Z-2012-0717-04) on July 27, 2012.

TSIA is the trade association of the semiconductor industry in Taiwan. More information about our organization can be found at <http://www.tsia.org.tw>

We are writing in support of the comments filed on October 11, 2012 by several technology associations based in the United States. The organizations are the Information Technology Industry Council (ITIC), TechAmerica, the Consumer Electronics Association (CEA), and the Semiconductor Industry Association (SIA) in the United States. The members of TSIA have reviewed the comments of these other technology associations and we endorse these comments. As discussed in detail in those comments, we believe that these proposed regulations set forth a burdensome and subjective regulatory scheme that will be infeasible and expensive for manufactured products such as semiconductors. In addition, we believe that some requirements may represent a technical barrier to trade (TBT) under the rules of the World Trade Organization (WTO), and could result in the disclosure of trade secrets and confidential business information (CBI).

We appreciate the opportunity to provide input on these proposed regulations.

Sincerely,

TY Wu, President

FM Hsu, ESH Committee Chair

Taiwan Semiconductor Industry Association  
Rm1246, Bldg 51, 195, Sec. 4 Chung Hsing Rd., Chutung, Hsinchu, 310 Taiwan ROC  
URL: <http://www.tsia.org.tw>

contact: Ms. Celia Shih  
email: [celia@tsia.org.tw](mailto:celia@tsia.org.tw)

本信件可能包含工研院機密資訊，非指定之收件者，請勿使用或揭露本信件內容，並請銷毀此信件。

This email may contain confidential information. Please do not use or disclose it in any way and delete it if you are not the intended recipient.

Electronics Industry Comments on Proposed Regulation on  
Safer Consumer Products  
(July 2012)

ITI, TechAmerica, the Consumer Electronics Association (CEA) and the Semiconductor Industry Association (SIA), are pleased to provide these comments on behalf of the information technology, consumer electronics, and semiconductor industries on the Proposed Regulation for Safer Consumer Products (Proposed Regulation). We appreciate the opportunity to provide input on the Proposed Regulation and we look forward to working with the California Department of Toxic Substances Control (DTSC) as the Regulation is finalized and implemented.

Our member companies have long been leaders in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design, energy efficiency and product stewardship. ITI, TechAmerica, CEA and SIA are submitting these comments in order to promote the development of consumer product regulations that will expand on the environmental efforts of our member companies and drive improvements in environmental performance and ensure California's continued leadership in technological innovation.

**General Comments:**

We offer specific comments on sections of the Proposed Regulation below, but wish to offer several overarching comments. As we have mentioned in our previous comments, when AB 1879 was signed into law by then Governor Schwarzenegger, Governor Schwarzenegger specifically noted that AB 1879 and its implementing regulation were to draw on "lessons learned" in other jurisdictions, and take into account programs in other states, countries and regions, such as the European Union, and build upon their experience, data and expertise.

Unfortunately, it does not appear that the Proposed Regulation was developed with the perspective of learning from other jurisdictions' experience in developing chemical regulations. In previous comments, we have provided several examples of how such experience and expertise can be used to improve the Proposed Regulation; however, we have seen little improvement in this area. We suggest that the DTSC consider how other jurisdictions regulate chemicals used in consumer products when redrafting these regulations.

Overall, the electronics industry considers the Proposed Regulation to be an improvement over the informal draft regulations that were released in 2011, but we still have significant concerns with the Proposed Regulation. The Proposed Regulation presents a very onerous and potentially costly regulatory scheme that is predicated on significant paperwork requirements, for both industry and the DTSC, and an overreliance on testing that, especially for manufactured products (e.g., articles), will be difficult and expensive, while providing few, if any, environmental benefits.

The electronics industry is concerned that the Proposed Regulation is overly subjective and needs to be more focused on objective and standardized processes. It is critical that any person doing a regulatory analysis or determination under these regulations will be able to reach a similar conclusion. Currently, the Proposed Regulation is overly deferential to the DTSC and too discretionary in several areas, mostly but not exclusively in the prioritization and regulatory response areas, for which we've provided specific comments.

While we appreciate that the DTSC is looking for flexibility to allow for changes in science and in response to new information in chemicals management, in many cases, the overly-flexible language only provides ambiguity, does little to provide the regulated community with regulatory certainty, and could provide a disincentive to voluntary actions in the marketplace. While the DTSC has recently assured industry that the regulatory assessment process will be consistent across individual cases, future administrations may take different approaches if given the regulatory authority to do so. We suggest that, in particular, the DTSC provide clear processes for prioritization and clear triggers for regulatory actions. There should also be a provision allowing for the regulations to be revisited if there are changes in the scientific or economic landscape.

The electronics industry suggests removing the term "homogenous material" from the Draft Regulations, but retaining the concept and intent of targeting specific materials within a larger consumer product by modifying the definitions of "component" and "consumer product." While we agree with the intent of regulating specific uses of a material in certain and clearly defined cases, the term "homogenous material" has been problematic, even the improved version that is contained in the European Union's revised RoHS Directive (termed "RoHS Recast")<sup>1</sup>. In our comments, we suggest that, by modifying the definitions of "component" and "consumer product," the DTSC will have the ability to target chemicals of concern in specific materials, but will not propagate a still problematic definition contained in another regulatory program.

We believe that several provisions contained in the Proposed Regulation, especially those requiring testing, may constitute a technical barrier to trade) under the World Trade Organization's Agreement on Technical Barriers to Trade<sup>2</sup>. When suggesting restrictions on the use of any chemicals, the DTSC must be able to list acceptable, internationally-recognized testing methods that will allow manufacturers to demonstrate compliance with the regulatory requirements. However, testing should not be viewed as the only means of demonstrating compliance as there are often less costly and destructive means to determine regulatory compliance, such as supply chain disclosures and material declarations.

The electronics industry continues to oppose the use of Certified Assessors in Article 8. We provide more detailed comments on this Article below, but we believe that the use of Certified Assessors will not provide any certainty to the DTSC, public or manufacturers that the assessment has been done correctly and thoroughly, and can, in fact, raise significant legal issues for the Assessors, the manufacturers and the DTSC. The use of a Certified Assessor, with DTSC review and acceptance of the

---

<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF>

<sup>2</sup> <http://www.worldtradelaw.net/uragreements/tbtatreement.pdf>

Alternatives Assessment (AA) results, raises a basic question up for debate as to who is ultimately responsible, and subsequently liable, for the selection of materials in a product. We have stated repeatedly in previous comments that an AA is only one data point of several that inform the decision of which materials are selected for use in a product. We believe that the DTSC is erroneous in assuming that there will be a clear “winner” material in an AA that should be used above all others. It is rarely the case that an assessment will provide an overwhelmingly clear answer.

Finally, the Proposed Regulation raises several concerns related to trade secret and confidential business information (CBI) protections. In several parts of the Proposed Regulation, requirements are established that would require manufacturers to supply information to the DTSC, such as specific information related to sales and manufacturing processes, which are often closely-held, private business information. ITI, TechAmerica, CEA and SIA recommend that the DTSC review the information that is being requested and consider the potential trade and business ramifications of divulging such information. We make specific comments on this important issue in our review of specific sections of the Proposed Regulation below.

### **Specific Comments by Section:**

#### **Article 1. General**

##### **Section 69501.2 Definitions**

“Homogenous Material” – Because of the difficulty with the term “homogenous material” we suggest removing this definition (part 34) from the regulations in its entirety. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but as mentioned previously, the definition of “homogenous material” is not viewed as well defined in the EU RoHS Directive by all stakeholders, and attempting to harmonize with a term that is problematic to some in the industry will make compliance difficult for both the Department and manufacturers.

Additionally, while we support the continued exclusion of “Historic products” from the definition of “Consumer product” and therefore from being subject to these regulations, we note that the proposed definition fails to include any necessary repair or replacement parts to maintain such products. The continued manufacture and availability of repair and replacement parts without being subject to these regulations is critical to maintaining the cost-effective support and operation of these products for our customers. As noted in the Initial Statement of Reasons (ISOR), the definition of “manufacture” (40) is intended to also exclude “replacement parts” as may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference replacement parts. We recommend below that these definitions be modified accordingly.

Thus, we recommend that the definitions of “Component” and “Consumer Product” be changed to read:

(21) “Component” means a uniquely identifiable part, piece, assembly, subassembly or uniquely identifiable material within a single part, piece, assembly, subassembly of a consumer product that:

- (A) Is required to complete or finish an item
- (B) Performs a distinctive or necessary function in the operation of a product or part of a product

(C) Is intended to be included as a part of a finished item

(22)(A) “Consumer product” or “Product” means the following:

1. A “consumer product,” including component, as defined in Health and Safety Code section 25251, that is identified under section 69503.4(a)(2)(B), as the minimum required focus of an AA.

(B)1. “Consumer product” or “Product” does not mean any historic product.

2. “Historic product” means a product that ceased to be manufactured prior to the date the product is listed as a Priority Product, and includes its service, replacement and repair parts regardless of when manufactured that are necessary to maintain and/or repair the historic product.

(C) “Consumer product” or “Product” does not mean a product previously owned or leased by someone other than the manufacturer, importer, distributor, or retailer of the product.

(40) “Manufacture” means to make, produce, or assemble. “Manufacture” does not include any of the following actions, unless the action results in the addition, or increased concentration, of a Chemical of Concern, or replacement of a Chemical of Concern, in a product:

(A) Repair or refurbishment of an existing consumer product, including the manufacture of repair or replacement parts;

(B) Installation of standardized components to an existing consumer product; or

(C) Making non-material alterations to an existing consumer product.

Additional definitional recommendations:

**(26) “End-of-life”** – This definition would encompass stages of a product life cycle where products may be reused or refurbished and, therefore, are not considered to be at their “end-of-life.” This is an important distinction for electronic products. We suggest tying the end-of-life to when a product enters the waste stream and no longer has useful life.

We believe that DTSC could address this concern by changing the definition of (26) to read:

(26) “End-of-life” means the point when the product is at the end of its useful life, and is discarded for recycling or disposal by the consumer.

**(52) “Reliable information”** – We are concerned that the definition of “reliable information” assumes that too much information is *de facto* deemed “reliable” simply because it has been published in peer reviewed journals or by state regulators. We believe neither of these scenarios automatically make information “reliable” We recommend that, due to the limitations of peer review<sup>3</sup> and state agency reports, that a process for disputing the reliability of such information be included. .

Recommendation:

We suggest revising the definition of “Reliable information” to read as follows:

---

<sup>3</sup> See OMB’s Information Quality Guidelines, 67 Fed. Reg. 8452, 8455 (Feb. 22, 2002).

(52) (A) “Reliable information” means a scientific study or other information that is one or more of the following:

1. Published in a scientifically peer reviewed report or other literature;
2. Published in a report of the United States National Academies;
3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
4. Conducted, developed, submitted, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

(B) Interested parties may dispute the information from the Department in public workshops or during comment periods.

## **Section 69501.2. Duty to Comply and Consequences of Non-Compliance**

(a) Duty to Comply.

Subpart (a)(2) should allow a consortium, trade association, public-private partnership, or other to apply for technology-specific exemptions under sections 69503.6 and 69503.7, rather than each company being required to do so independently. Thus, to minimize the compliance burden on individual companies, we recommend the following:

Change subpart (a)(2) to read:

The requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity.

(b) Manufacturer and Importer Options.

(b)(1) and (2) - These notification requirements will only serve to burden manufacturers and the Department, with no discernible benefit to the environment, and (b)(2) will significantly increase the burden of placing new products on the market. The Department has consistently stated that the regulations must reward innovation. However, these requirements will significantly slow the introduction of new products in the California market.

We believe one way that DTSC could address this concern is as follows:

Change subpart (b) (1) and (2) to read:

if a priority product is either removed from commerce in California, or if the product has been redesigned to remove or reduce the chemical(s) that were the basis of an AA or replaced, the manufacturer must be able to demonstrate to the Department’s satisfaction, upon request, that the product has been removed from commerce or redesigned or replaced in the marketplace.

A similarly simplified process should also be applied to the Retailer Option under subpart (c).

#### **Section 69501.4. Chemical and Product Information**

The Department should not request information from responsible parties unless publically-available sources of information have been exhausted. We suggest that the Department specify that the approaches outlined are in order of preference.

It is not clear how the Department will handle cases where responsible parties do not have the information being requested or if there is conflicting information between sources of information; in particular for information submitted by responsible parties.

#### **Article 2. Chemicals of Concern Identification Process**

##### **Section 69502.2. Chemicals of Concern Identification**

While we appreciate that the lists presented in the regulation have been pared down from previous versions, the list of chemicals identified by the list of lists in § 69502.1 will still be in excess of 1,000 chemicals. We are concerned that the purpose of this list will be misconstrued by companies in the supply chain as well as by governments, NGOs, and in particular by members of the general public whose lack of understanding with this complex regulation may lead to unfounded fear. It is very likely that the chemicals identified by this process will have a stigma attached to them that will cause their use to be unnecessarily challenged or questioned, even though the chemicals may have already undergone an assessment or have been determined to be safe in specific applications. The electronics industry believes that the approach suggested by Mr. Mike Rossi of the Governor's office is appropriate for the chemicals of concern identification process, which is reflected in our recommendation below.

Further, we believe that there should be different terms to address specific instances in the regulation. The term "Chemical of Concern" (CoC) currently means a chemical on the list per section 69502.2 that exhibits a hazard trait; the chemical paired with a specific product and the focus of the alternatives assessment in sections 69503.4 and 69503.5; and could mean any chemical requiring reporting to the Department in section 69505.5 or disclosure in consumer information in section 69506.4. Using different terms in different instances will clarify what the Department is referring to at any part in the regulatory process.

Recommendation:

The electronics industry recommends a two-part process for identifying chemicals of concern. First, a list of "Chemicals of Interest" are developed using the process in Section 69502.2, then a pared-down "Chemicals of Concern" list is developed from the "Chemicals of Interest list" and specific factors identified by the Department. Finally, a "Priority Chemical" is a chemical that has been pared with a priority product and is the focus of the Alternative Analysis. This Priority Chemical will also be the focus of any regulatory actions that stem from the AA.

#### **Article 3. Chemicals of Concern and Consumer Product Prioritization Process**

### **Section 69503.1. Applicability**

The Statement of Reasons document for these regulations is very clear that products that do not contain a chemical of concern are not subject to the requirements of this section. However, the regulations are not as clear on this point.

Recommendation:

There are two options that we believe address this concern.

Option 1 - Add a second sentence:

This section is not applicable to products that do not contain one or more chemicals of concern.

Option 2 – Modify the definition of Priority Product:

(48) “Priority Product” means a product containing one or more Chemical(s) of Concern as identified and listed as a Priority Product by the Department under section 69503.4.

### **Section 69503.2. Priority Products Prioritization Factors**

The regulations have several factors that include the concept of exposure, but exposure of a chemical of concern is not a factor in the prioritization. While the regulations do contain subpart (a)(1)(B), the regulations seem to assume that any exposure to a product equates to exposure to the chemical of concern, so this subpart relates to exposure to the product, not to the chemical of concern.

“Containment of the Chemical” within the product is included in the product prioritization criteria in subpart (a)(1)(B). As described in the ISOR, “how the Chemical of Concern is contained or bound during the use of the product determines, in part, the amount of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user, in which case, there is little to no exposure as a result of use of the product.” These are meaningful and practical ways to assess exposure to a chemical in a complex product or article and should be retained. We suggest that the Department add language in subpart (a)(1)(B) to clarify that “containment” includes the concept of accessibility as described in the ISOR. “Accessibility” is a commonly-accepted term with well-established tests for whether a part of a product is accessible or not for chemical exposure purposes, such as the test used by the Federal Consumer Product Safety Commission.<sup>4</sup>

Finally, subpart (a)(1)(B)(4)(a) discusses chemical exposures during manufacturing. The Department has been consistent in stating that these regulations cover consumer products and chemicals. Exposures during manufacturing processes are already covered under existing authority by the federal Occupational Safety and Health Act (OSHA), and should not be included in these regulations.

Recommendation:

---

<sup>4</sup> <http://www.cpsc.gov/about/cpsia/inaccessiblefr.pdf>

We recommend that this section, in particular subpart (a)(1)(A), be greatly simplified and specifically mention exposure as a factor. One way that DTSC could address this concern is as follows:

Change (a)(1) to read:

Adverse impacts and exposure. The Department will consider the adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to the physicochemical properties, environmental fate, hazard traits and the possibility and likelihood of exposure to the Chemical(s) of Concern through reasonably foreseeable use and abuse of the product.

Additionally, we believe further clarity could be provided by the following:

Change (a)(1)(B)(4)(d) to read:

Containment of the Chemical(s) of Concern within the product, which includes whether the Chemical(s) of Concern is in an inaccessible component within a product.

Subpart (a)(3) also has the Department “considering” other California and federal laws. The electronics industry strongly believes that, as in previous drafts of the regulations, devices that are already regulated for a particular chemical use must be exempt from these regulations. The potential for multiple, conflicting and confusing regulatory schemes is too great to simply make those a factor for consideration. At the least, there should be considerations for exempting products that are previously regulated under other international or federal chemical regulatory regimes. There should be a presumption that chemical risks have already been reduced in such cases.

Subpart (b) lists key prioritization factors the Department will consider. We believe this process is more complicated than in previous drafts, and suggest the Department consider expanding these key criteria to make it clearer when a product may meet them.

Recommendations:

We suggest the Department give priority to products meeting the following criteria:

- (1) The chemical of concern in the product have a significant potential to cause adverse public health or environmental impacts;
- (2) The product is widely distributed in commerce and widely used by consumers;
- (3) There is significant potential for public and environmental exposures to the chemical(s) of concern in the product in quantities that can result in adverse public health or environmental impacts; and
- (4) For assembled products, the product contains one or more chemicals of concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts during intended and reasonably foreseeable use.

### **Section 69503.3. Process to Evaluate Products Using the Prioritization Factors**

While this section is labeled a process, the electronics industry does not believe this is truly a process as required by AB 1879. As we mention in our general comments on the regulations, we are concerned that any person, or any administration, conducting this process will not generate similar results. While we appreciate that different entities (i.e., manufacturers vs. regulators) will have different assumptions and potentially different expertise, the process should still be sufficiently standardized so that anyone who does the process in good faith will come up with a similar result. We are not convinced that this is the case with the SCP regulations. There is simply too much discretion and variation in the steps enumerated in this section.

We recommend that the DTSC revert to the flow chart process that the DTSC used previously. A flow chart approach or, at least, a step-wise approach will be more systematic and less subjective than the current proposal.

Subpart (f)(1)(B) allows the Governor's office to potentially skip all of the Article 2 Chemical of Concern identification, and to unilaterally give priority to a chemical without any process or public input. While the final list would be open for public comment, it would be too late in the process to respond to any potential issues stemming from a Governor's Executive Order. We believe this is too broad a mandate and needs to be either removed or moved to the CoC identification in 69502.2.

### **Section 69503.4. Priority Products List**

Subpart (a)(2)(B) introduces the concept of the highly durable product. While we appreciate the intent of this term, we are not sure that it will adequately distinguish between formulated products and articles, and we believe that the limits placed on the department for selection of components and materials (10 per product every 3 years) are not useful. Alternatives assessments on articles are often very long and complex undertakings. For example, the US EPA Design for Environment program has been investigating alternatives for decaBDE in plastic casings. This assessment has taken over 3 years and has consumed several hundred thousand dollars, and has just gone out for public comment. While we recognize that this case is more complex than many others, it is still not unusual for assessments on electronic products to take two – three years. Having a limit of 10 things every three years will still potentially have manufacturers in a constant loop of mandated assessments.

Subpart (d) notes that the Department may respond to some or all public comments. We believe that for a truly credible process, the Department has the obligation to respond to all public comments. We do recognize that the response will be, in some cases, that a comment is without merit.

Recommendations:

(a)(2)(B) – Per our comments on homogenous material in Section 69501.1, we recommend changing (B) to read:

(B)1. If applicable, the component(s) and/or uniquely identifiable material(s) within a component, to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA.

2. For each Priority Product that is a highly durable product, the Department shall in all cases specify the number of component(s) and/or uniquely identifiable material(s) within a component to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA. For each listed highly durable product, the Department shall specify no more than ten (10) components and/or uniquely identifiable materials per product every three (3) years.

### **Section 69503.5. Alternatives Analysis Threshold Exemption**

As mentioned in comments to previous Draft Regulations, we believe that the inclusion of cumulative concentrations (in subpart (d)) will add ambiguity to the regulations that will make it very difficult for the Department and manufacturers to determine compliance with these regulations. For example, if a chemical gets reclassified or a new chemical of concern gets added to an existing priority product, then industry and DTSC personnel will have to re-calculate all the existing threshold level summations as the grouping of chemicals subject to the threshold will change. Further, manufacturers will not be able to use existing data and compliance systems, which are all based on single chemical thresholds, to ensure compliance with these regulations. This will delay DTSC's ability to quickly and efficiently implement the new regulation as both industry and the agency will be required to develop innovative new business processes and/or software tools that are capable of calculating the summation of chemicals vs. applying the threshold to a single chemical. This will divert valuable agency resources to focus on documenting that chemicals are not present in products from the primary purpose of the regulation which is to identify safer consumer products.

Finally, it is not always possible to analytically quantify all chemicals in a consumer product, especially for assembled products which may have matrix interferences, or some inorganic compounds with only analytical methods for the elements but not the full chemical compound. Therefore, having the threshold potentially set at a cumulative sum of chemicals and not an individual chemical increases the complexity of quantification to a sum total as more and more chemicals may fall into the category of "unquantifiable." As the department adds more chemicals to a priority product, the cumulative sum threshold will become more and more difficult to quantify as the thresholds get smaller and smaller going below any ability of analytical detection limits. This uncertainty will be exacerbated in more complex assembled products and will only make the compliance demonstration and/or enforcement more difficult.

The electronics industry acknowledges the importance of considering cumulative chemical effects, however, we believe this should be considered during the product prioritization phase and can be addressed through regulatory responses, but it is not appropriate for a threshold determination.

### **Section 69503.6. Alternatives Analysis Threshold Exemption Notifications**

The electronics industry continues to believe that these minimum threshold exemptions should be self-implementing. The amount of information being requested by the Department to demonstrate that the levels are below that which should be regulated will be overwhelming to the regulated community and the Department. Additionally, there is a dependence on testing results to “prove the negative” that a chemical is not in a product, where a compliance assurance system, which may include but does not require testing results, is in most cases much more practical for manufacturers to manage the content of their products and the Department to ensure compliance with the regulations.

Recommendations:

The electronics industry suggests that much of § 69503.6 be deleted, and replace with a compliance assurance process where the Department may request information from the manufacturer.

In creating a program to ensure compliance with the threshold exemption, the Department should remove the implication at § 69503.6(a)(5) and (a)(7) that only analytical testing results are appropriate substantiation that a product meets the threshold exemption. Given the sheer number of chemicals of concern based on regulations and customer restricted/banned substances lists, testing for all of these chemicals is cost-prohibitive. Therefore, manufacturers commonly rely on supplier certifications regarding purchased material content to understand product ingredients and impurities, and cannot routinely test all purchased materials or finished goods. Responsible manufacturers augment supplier information with testing when knowledge of the chemistry of the product indicates probable presence of chemicals of interest, or when there is cause to doubt the veracity of the supplier certification. This method has been widely used to determine compliance with international chemical restriction laws and regulations and is sufficiently rigorous and credible to provide a model for the Safer Consumer Products Regulation.

### **Section 69503.7. Priority Product Notifications**

As written, this section will inundate the Department with information as soon as a Priority Product list is published. The Department should reconsider the reporting and notification requirements in the regulations, considering the burden on the manufactures to produce this information and the Department to receive process and respond to it. It is not clear why the Department would need all of the information requested, in particular all of the information in subpart (a)(2).

## **Article 4. Petition Process for Identification and Prioritization of Chemicals and Products**

### **Section 69504. Applicability and Petition Contents**

We are concerned that the requirement of subpart (b), that a chemical be off all lists, is an overly high hurdle to clear to request a petition. The lists in section 69502.2(a) are all updated on different cycles, with some taking significantly longer than others to refresh. If there is significant new information, it is unlikely that it will change all of the lists within a reasonable time frame. The section should allow petitioners to remove Chemicals of Concern on a showing of “preponderance of the evidence” that the scientific evidence supports removal.

Recommendation:

We believe one way that DTSC could address this concern is as follows:

(b) Change to read:

A person may not petition the Department to delist any chemical identified as a Chemical of Concern unless that chemical has been removed from at least one list identified in section 69502.2(a).

#### **Section 69504.1. Merits Review of Petitions**

This section contains a list of factors the Department will consider in making a determination of whether a petition will be denied or granted. However, the criteria listed are only applicable to petitions to add substances to the Chemical of Concern list. There should be factors for how a chemical may be petitioned for removal from the CoC list.

Further, we are concerned with the subjectivity of this section. As with previous sections, there should be assurances that the petitions will be reviewed with a process that is dependent only on the science and merits of the review. We suggest that the Department develop a process or explanation of how the factors will be applied so that petitions may be reviewed more consistently based on an objective determination.

#### **Article 5. Alternatives Analysis**

##### **Section 69505. Guidance Materials**

The electronics industry contends that not all methodologies to perform an assessment are of equal caliber. Therefore, we are concerned that a process that has less rigor than necessary may be promoted and accepted as guidance by the department, and processes that are applicable to one type of products but not others may be used by assessors that do not understand the products and how they are produced. Therefore, we suggest that the Department allow for public input into the guidance materials when they are posted.

##### **Section 69505.1. Alternatives Assessments: General Provisions**

As mentioned in our general comments, the electronics industry feels that several of the timelines presented in the Proposed Regulations are too short to be workable. We believe that subpart (b)(3)(C)

is an example of this. Some of our associations' member companies have done assessments using the guidance in previous drafts of the regulations, and the preliminary steps took longer than 180 days. For simpler products, it is possible that a shorter timeframe is practical, but for high tech products with a complex supply chain, 180 days is too little. We suggest allowing the Department to set due dates when the Priority Products List is published. Allowing flexibility for the due dates may provide manufacturers with the opportunity to work with their supply chain and develop meaningful AAs.

As we mention in our comments to Article 8, we believe the requirements for a Certified Assessor in subpart (e) should be removed. Notwithstanding our objection to the use of Certified Assessors, we further believe that the 2 year implementation is unworkable. If the department proceeds with a Certified Assessor program, the timeframe of 2 years from the effective date of the regulations is unworkable. For the first set of priority products, a manufacturer will start the AA before 2 years is over, but may not have been able to complete it. These manufacturers should not have to switch assessors mid-stream. The DTSC should instead allow that the AA's for the first round of priority products do not require a Certified Assessor.

Subpart (g) requires that manufacturers who reformulate their products submit significant information to show that the chemical of concern is no longer in the product. We believe that this is another example of an overly-burdensome and large information request that manufacturers will be required to prepare and the DTSC will be required to process with little or no benefit to the environment. We believe that as with the AA threshold, if the manufacturer reformulates the product, no further reporting should be due. If the DTSC does feel some notice is necessary, a simple notification with the contact information and a statement that the product no longer contains a chemical of concern should be adequate. As we have mentioned previously, it is impossible to "prove the negative" that a chemical is not present, and the regulations are overly reliant on product testing to demonstrate compliance. There are many examples of other reliable and credible ways to demonstrate conformance, including supply chain declarations and internal process controls. If the DTSC is going to require testing to demonstrate compliance, it is incumbent on the Department to specify which tests are acceptable to show compliance.

## **Section 69505.2. Analysis of Priority Products and Alternatives**

Subpart (b) notes that a responsible entity may submit an abridged AA report if an acceptable alternative is not "available or feasible." However, the Department does not specify thresholds for these terms. The Department should provide some guidance for feasibility in this section or in section 69505.3. Additionally, subpart (b) indicates that a responsible entity cannot do an Abridged AA Report without first doing a full Stage 1 study. We believe that a responsible entity should be able do an Abridged AA Report without first going through the process of a full Stage 1 study if they rely on information from other regulatory entities or trusted bodies to show that there are no viable alternatives.

Additionally, it is not clear how the Department will approve research and development (R&D) plans under this part and section 69505.3. It is unlikely that the Department will have the industry-specific expertise necessary to adequately review and approve R&D plans.

Subpart (d) allows for a responsible entity (manufacturer) to select a different alternative from the one identified in the Final AA Report. As we note in our general comments, this may raise the question of who is responsible for the material content of a product. It is not clear who will be ultimately responsible for a product material content if a manufacturer disagrees with the Certified Assessor. This subpart allows the manufacturer to assume that responsibility, but it is not clear why they may want to do this if a Certified Assessor has already made a recommendation.

Additionally, subpart (d)(1)(B) notes that the revised Final AA Report must be submitted to the Department 60 days prior to placing the product in the stream of commerce. What is the responsibility of the manufacturer if the proposed selected alternative is already in the stream of commerce?

### **Section 69505.3. Alternatives Analysis: First Stage**

Subpart (a) is an example of our comments in Section 69502.2, where different terms are needed to identify chemicals at different parts in the process. Using the same term depending on when referenced in the regulations is confusing. We recommend developing separate terms for these concepts in the regulation.

Subpart (b)(1)(A) notes the responsible entity must identify all legal requirements associated with the use of the product. However, the manufacturer is not likely to have this information. The manufacturers will have all compliance information for the manufacture of the product. We believe that this is what the DTSC is asking for in this section, but it should be made clear.

Subpart (b)(2)(A)1 states that alternatives must “eliminate or reduce the concentration” of the chemicals of concern in the product, but does not provide any threshold for this. As written, a trivial reduction of the CoC in the product through any means would meet this requirement. We suggest using the term “reduction in use” of the chemical of concern which will remove much of the ambiguity with the term.

The electronics industry is concerned with the requirement in (b)(2)(A)2 that a manufacturer shall consider alternatives posted for consideration by the Department. It is possible that a manufacturer has already considered these alternatives and should not be subject to doing so again, or based on the technical expertise of the manufacturer, they may be able to reject an alternative without the need for a full assessment. We suggest that the Department should not suggest alternatives, allowing the manufacturer to perform the AA, however, the Department could require the manufacturer to review and potentially explain why an alternative presented by the Department is not viable, but to require them to consider these in their AA is overly prescriptive.

### **Section 69505.4. Alternatives Analysis Second Stage**

In subpart (a)(2), the Department assigns all responsibility for collecting and using available information and tools on the responsible entity; however, as we have pointed out, a third-party Certified Assessor may actually be the entity performing the assessment, and the Department has reserved the right to agree or disagree with the assessment results. As we have mentioned several times, this can potentially pose a significant conflict, and it is not clear who is ultimately responsible for the results of the AA. It is possible that the Department or Certified Assessor may second guess the manufacturer (responsible entity) and it is not clear what recourse, if any, the manufacturer has in these cases.

The electronics industry is concerned that the economic impacts in subpart (a)(2)(C) do not include research and development costs of using new materials, as well as performance and other testing (for example, for medical devices). These costs are important factors and should be part of the AA. Further, the Factors in subparts (B) and (C) do not include performance of the selected alternative.

Step 2 (subpart (b)) will require the use of the tools and guidance materials identified in section 69505. It is important to realize that these tools will provide important information, but will not be conclusive regarding the final decision or assessment. Weighting of the factors involved will have a significant effect on the outcome, and only the technical expertise of the manufacturer and assessor will be able to adequately weigh factors in the assessment. As we mentioned previously, there will rarely be a clear-cut “winner” material in this process, and only, after reviewing all the evidence, will the assessors and manufacturers be able to make a final decision based on the totality of the evidence. While the manufacturers will attempt to provide justification to the Department, it is not clear that the Department will agree with this justification, or for that matter, the outcome of the assessment.

Subpart (d), considering additional information, should be performed before an alternative is selected (currently subpart (c)).

The timelines for implementation of the alternative (in several sections, but mostly section 69505.5), are very tight and manufacturers, in many cases, may not be able to implement an alternative in proposed timeframe. For example, communications and medical devices have, on average, a four-year cycle between when a product is first designed to when it is formulated, assembled, and tested for performance and compliance with existing regulations. Further, smaller companies often do not have the “pull” to affect changes in the supply chain; in fact, large companies (our associations represent many of the world’s leading high-tech companies, as well as smaller or medium enterprises) often have trouble affecting changes in the supply chain since many companies are located overseas. This may lead to an outcome where certain globally-available products will not be available for sale in the State of California.

### **Section 69505.5. Alternatives Analysis Reports**

(a) – The term “sufficient information” is used several times in this section, but is not defined in the regulations. It is not clear how the responsible entity can provide information for an appropriate due date. Section 69505.4(e) states that a responsible entity shall propose regulatory responses as part of the AA, then section 69505.5(a)(4) states that the Department will determine an appropriate regulatory

response. What is the process if the Department disagrees with the Certified Assessor/Responsible Entity proposed response?

(d) – It is very likely that the manufacturer will not have much of this information, and it is unclear why this information would be necessary for an environmental, health and safety alternatives assessment. Manufacturers typically sell to distributors or distribution centers, and they determine what products go where. Additionally, much of this information, especially the supply chain and manufacturing locations, is likely classified as “trade secret” information.

Recommendation:

Remove these reporting requirements from this section. If this information is necessary, the Department can obtain it in the process outlined in § 69506.9.

(f) – The Regulation should not dictate how information is presented in the Alternatives Analysis Reports. It is not possible, in all cases, to present a matrix or even an easily-understood visual comparison. Very complex AAs may not lend themselves to one particular type of information format.

Recommendation:

Simplify section (f) and remove most requirements for how information is to be presented. The Department should consider adding a subpart asking for clarification on a section of the AA, rather than simply asking for more information.

(g) – As mentioned in several sections, determining the relevant comparison factors is a somewhat subjective exercise and depends greatly on technical expertise and knowledge of the industry being assessed. It is not clear what will happen if the Department disagrees with the weighing and comparison of the factors.

(j) – The list of all chemical ingredients is not always available for complex parts and products, or it may be confidential information not available to the responsible party or not relevant to the AA. The further information (subparts 1-6) is potentially a significant amount of information for the manufacturer to prepare and Department to process, which may not be relevant to the AA for the chemical-product pairings. We recommend simplifying this section and paring the information required to the chemical/product information used in the AA and relied upon to make the final assessment.

(k) – As per our general and subsequent comments, it may take several years to complete these sections, and it is not clear that the deadlines in this section are practical. We recommend providing more flexibility, especially for more complex products.

## **Section 69505.6. Department Review and Determinations for AA Reports**

It would seem that this section obviates the need for Certified Assessors in Article 8. If the Department is reviewing all AAs to ensure compliance with this section, it is not clear what role the Certified Assessor will serve in assuring the quality and thoroughness of the AAs.

## **Article 6. Regulatory Responses**

### **Section 69506. Regulatory Response Selection Principles**

As written, this section does not require the Department to consider the five factors listed in subsection (c) when determining which regulatory response may be appropriate, if any. Rather, DTSC is only required to give preference to regulatory responses that provide the greatest level of “inherent protection.” However, less inherent toxicity in a product should not be the only factor DTSC considers; there are many other factors involved when a decision is made to use a particular chemical in a product. Thus, DTSC should be required to consider all five factors listed in subsection (c) by eliminating the permissive language on Page 52, Line 15 and replacing it with “...the Department shall consider all of the following factors.” We believe that reasonable consideration of all five factors prior to imposing any regulatory response will be critical if the program is to be practical, meaningful, and legally defensible. Additionally, the Department should consider existing regulations when determining a regulatory response.

Recommendation:

Add the following line to subpart (c):

(c)(6) Existing regulations for that product

Finally, while we appreciate that DTSC has included a cost-effectiveness consideration in (c)(2), we are concerned that the Department will not have the information necessary to do an effective cost-benefit analysis of the regulatory response.

### **Section 69506.1. Applicability and Determination Process**

We believe that this section should include a minimum timeline for when a regulatory response will be required to be implemented. Given the complexity and significance of the regulatory response options at the Department’s disposal, we believe that regulated entities should be given a minimum of one year(?) after the receipt of the final regulatory response determination notice to implement the regulatory response. This timeline should increase depending on the severity of the regulatory response selected.

### **Section 69506.2. AA Report Supplemental Information Requirements**

As written, we believe that this regulatory response would act as an overly broad and unnecessary mandate on companies, giving the Department the ability to demand any information from a company on any timeline it chooses. We suggest the following changes:

§ 69506.2 (a) – Change to read:

(a) The Department may require a responsible entity to provide, within a reasonable time frame specified by the Department, information supplementary to the Final AA Report...

§ 69506.2 (b) – Change to read:

(b) The Department may require a responsible entity to obtain or develop, within a reasonable time frame specified by the Department, information that is reasonably attainable by the entity to fill one or more information gaps identified in the Final AA Report...

In addition to these changes, we believe that the information demands made by DTSC should be targeted and reasonable, rather than overly broad. Furthermore, once the required information has been provided, that action should fulfill the regulatory response obligation for a reasonable period of time, so that a compliant entity is not continuously required to generate more and more information.

### **Section 69506.3. No Regulatory Response Required**

It is not clear how this section relates to the product sales prohibition (Section 69506.6) and end of life management (Section 69506.8) response options. As currently written, it appears that § 69506.8, and potentially § 69506.6, will act as “default” regulatory responses and will be automatically implemented unless a finding is made that no regulatory response is required under this section. This is due to the language in both sections reading “except as provided in section 69506.3.” For obvious reasons, we believe that automatic triggers for any of the regulatory responses, including product information, will lead to unnecessarily burdensome results. Rather, DTSC should be required to carefully weigh and consider all of the factors delineated in § 69506(c) before deciding to impose any of its regulatory response options.

### **Section 69506.4. Product information for Consumers**

As written, it appears that this regulatory response will be automatically required unless no Chemical of Concern is present above the applicable threshold. This automatic trigger seems unnecessary and could lead to information saturation for consumers on a wide scale. This is especially true given the amount of information required by subsection (a)(1). This requirement also includes some information that the manufacturer may not even have available, such as (a)(1)(C), or that may be considered confidential business information, such as the importer information in (a)(1)(F).

It would also be very difficult to fit this much information on the product packaging, and retailers will not voluntarily provide a placard at the point of sale. As we have stated in prior comments, the physical labeling of products is an outdated and inefficient solution that makes little sense for many types of

products. Research continues to show that beyond immediate hazards, labeling of a product is an ineffective way to warn consumers of potential hazards. Furthermore, information/disclosure requirements should be done in the least restrictive manner possible. Manufacturers should have options to labeling by providing information channels to consumers through the use of websites, product manuals, or other options that make sense for their market and for the potential hazard.

#### **Section 69506.5. Use Restrictions on Chemical(s) of Concern and Consumer Products**

It is not clear how restrictions on the use of consumer products can be enforced. While information on use restrictions can certainly be made available, how would the Department ensure compliance with such restrictions?

#### **Section 69506.6. Product Sales Prohibition**

As stated above, it is not clear how the tie-in to Section 69506.3 would work in practice for the product sales prohibition response option. Additionally, how would the Department know which products contain any Chemical of Concern above the applicable alternative analysis threshold, and which do not? Again, there may not be tests available for determining the presence of a particular material in a product, making these determinations and enforcement challenging.

This section is also made unnecessarily burdensome by allowing the Department to still prohibit the sale of a product even if no viable alternatives exists (see subsection (d)(1)), and by requiring responsible entities to notify DTSC if their product does not contain a Chemical of Concern.

#### **Section 69506.7. Engineered Safety Measures or Administrative Controls**

We would suggest that this section use the term “accessibility” rather than “integrally contain” in subsection (b), as there are defined tests for accessibility, making it a more objective standard for compliance. Thus, page 57, subsection (b), line 16 would read: “limit accessibility to the Chemical(s) of Concern within the structure of the product or limit...”

Additionally, we believe that there needs to be thresholds for presence under subsection (b)(1) as Chemicals of Concern, metabolites, or others may be naturally occurring or have multiple metabolites. Simply requiring “presence” is too ambiguous of a standard to be useful here. Also, as written, presence in a single building would be sufficient to trigger administrative control under (b)(2), which we think is unnecessarily strict.

#### **Section 69506.8. End-of-Life Management Requirements**

As stated earlier, it appears that this regulatory response will be automatically imposed unless the Department finds that there is no need for any regulatory response under § 69506.3. Automatically requiring end-of-life management requirements would lead to unnecessarily burdensome results as

comprehensive product stewardship plans are very significant undertakings – logistically, financially, and otherwise – that should not be imposed absent careful consideration of all factors delineated in § 69506(c).

In addition, a one year time frame given in subsection (a)(2) is far too short for entities to implement the complex take-back schemes envisioned by this section, and it is unclear what financial guarantees, if any, would be adequate or available to entities under (a)(2)(A)(7). An additional concern is that this section does not differentiate between Business to Business (B2B) markets and consumer markets; there are viable markets for B2B recycling in many instances and the regulation should not undermine the free markets here.

The report required under (a)(2)(D) is also problematic. First, information on state sales and recycling is likely not available – most sales are done through distributors and manufacturers have no way to track what is sold in state. Additionally, and especially in the electronics industry, there is a vibrant post-consumer market, which would also make tracking recovery very difficult. And for durable products especially, which have lifespans of several years, the amount of goods recovered in a given year will have no relation to the amount of goods sold, which could give the impression to the Department that a program is performing poorly when in fact it is not.

Finally, it is unclear how a manufacturer might be able to prove to DTSC that an end-of-life management program is not feasible under subsection (d), though we agree that responsible entities should have the opportunity to show why they should be exempt from the requirement.

#### **Section 69506.9. Advancement of Green Chemistry and Green Engineering**

This section states that DTSC may “require” a manufacturer to conduct research and development, or fund a challenge grant, to design, improve, reduce the cost of, or increase the market penetration of, a safer alternative to a Priority Product. Since any given manufacturer might not have the resources to undertake such project, or might believe that such projects are not likely to be successful, a manufacturer should always have the option of discontinuing manufacture of the Priority Product. Section 69506.9 should be amended to provide explicitly that a manufacturer can choose to discontinue manufacturing a Priority Product instead of complying with any requirement issued pursuant to this section.

Additionally, many companies are engaging in research and development to achieve the goals specified in subparts (a) – (d), independent of the mandates in this regulation. These companies should be given credit for their independent efforts as it relates to this regulatory response, and any further mandated funding of R&D needs to come with IP protection for the responsible entity.

### **Section 69506.10. Regulatory Response Selection and Re-Evaluation**

As written, it is not clear what other situations DTSC is referring to in subsection (a), or why this section is needed to begin with. This section seems to remove any of the constraints imposed by earlier sections by stating that DTSC “may impose one or more regulatory responses ... to situations other than those specified in those section.” If that is the case, what could the Department not impose as a result of this section? We would request clarification on this point.

Additionally, the term “periodically” needs to be further defined or clarified in subsection (b). It would be unnecessary and burdensome to review regulatory responses too frequently. Entities need certainty with the responses they are required to comply with in order to do business.

### **Section 69506.11. Exemption from Regulatory Response Requirements**

As written, this section appears duplicative of work that the Department should have presumably already completed: the determination of conflicting or duplicative regulatory programs. If the product is already covered by California or other regulatory programs elsewhere, the product should already be exempt from these requirements. The responsible entity should not have to do an alternatives analysis and then put in a formal request to DTSC for exemption to demonstrate that a conflict exists with other regulatory schemes. That determination should have already been made.

We would suggest that a responsible entity be able to request and receive exemption for compliance with international law, such as RoHS or REACH, provided that the manufacturer can show compliance and that the international law will also provide health and environmental benefits.

### **Section 69506.12 Regulatory Response Report and Notifications**

As written, we believe this section is very problematic and fundamentally ignores the realities of supply chains and commerce. Manufacturers rarely sell directly to a retailer and thus will not be able to identify the retailers required to comply with subsection (a). We would suggest rather that the manufacturer notify whoever it is they are directly selling the product to if it is reasonably likely that the product will be sold in California. Then, the entity selling or distributing the product would be obligated to notify the appropriate retailers.

We believe the regulatory response notice to the Department required under subsection (c) is unnecessary, as DTSC should assume but confirm compliance as needed, such as by requesting compliance documentation.

## **Article 7. Dispute Resolution Proecesses**

### **Section 69507. Dispute Resolution**

It is not clear why articles 2, 4 and 10 are not subject to dispute resolution. We would think that the DTSC would welcome the opportunity to informally arbitrate any decision made pursuant to the

Regulation. We would think an information dispute process would help these articles; otherwise injunctive relief through the courts would be the only process open should a dispute arise. We suggest allowing all Articles to have some sort of administrative dispute process.

### **Section 69507.1. Informal Dispute Resolution Procedures**

We submit that allowing only 30 days to dispute an action, especially notice on the Department's website, is inadequate. In many cases, it may take 30 days for a responsible entity to realize they are involved and decide to dispute a posting. We suggest at least 90 days for this initial time.

### **Article 8. Accreditation Bodies and Certified Assessors**

ITI, TechAmerica, CEA, and SIA strongly assert that the Certified Assessor process as described in Article 8 will not serve to meet the goals of the Green Chemistry Initiative to ensure that 1) the alternative assessments are conducted by a person with all of the expertise necessary to adequately complete an assessment, and 2) that assessments will be done within the expected requirements for compliance with the law, thoroughness, and scientific rigor. For the reasons described in comments to previous sections and below, we urge the DTSC to remove Article 8.

Simply put, the Certified Assessor requirement will increase the costs to do the AAs, with absolutely no benefit. Most small companies will need to hire a third-party assessor, and larger companies will likely assume the expense of getting one or more of their technical experts certified. Most certified assessors will not have the specific product knowledge, especially if they are not experts in the industry they are trying to assess, to perform an assessment. Simply requiring a bachelor's degree in a scientific field and training on the requirements of these regulations will not ensure that the assessors will have the knowledge base to adequately perform an assessment. The assessor must have knowledge of the tools being used to perform the assessment (which will vary depending on the type of material and product assessed), knowledge of the industry being assessed, and the expertise to be able to weigh the factors and assess the information used to perform the assessment. No certification program will ever be able to provide this level of expertise.

As we have mentioned previously, the use of third-party certified assessors will likely create potential legal issues. For example, who will be liable for any material use decision based on the outcome of an assessment? What happens if the manufacturer disagrees with the assessor? What if multiple assessors are used (either in different manufacturers of the same product, or even within a single assessment) and the assessors disagree on the optimal outcome? Who will resolve any conflicting findings?

Recommendation:

Delete Article 8. The Department reviews all submissions for compliance with the regulations in section 69505.6 and has provided for a process to audit any AAs submitted under Article 9. We believe this is adequate protection to ensure that the assessments are done correctly, and the Department has the ability to review the AAs in depth for compliance, information quality and adequacy of the analysis.

## **Article 10. Trade Secret Protection**

### **Section 69510. Assertion of a Claim of Trade Secret Protection**

The electronics industry believes that a reasonable protection of confidential business information (CBI) is critical to innovation and competition in the market. As mentioned earlier, the Proposed Regulation would require manufacturers to supply a substantial amount of information to the DTSC, including sales and manufacturing process information. The submittal of such a broad range of potentially sensitive information increases the likelihood and frequency that a manufacturer may have to rely upon the regulation's trade secret provisions in order to safeguard its CBI.

Under Section 69510(a), a claim for trade secret protection will involve the submittal of extensive supporting information to the DTSC in order to substantiate its need for trade secret protection. A disagreement from the DTSC in the trade secret claim would mean that the manufacturer would need to cure the perceived deficiencies in the trade secret claim or seek judicial review in order to prevent the CBI from being released to the public (Section 69510.1).

This resource-intensive CBI claim process strongly emphasizes the need for the Department to carefully consider what information it truly requires from regulated entities throughout the Regulation. Thus, we urge the Department to limit submission requirements only to that information which is absolutely necessary for DTSC to implement the Regulation. This will help reduce unnecessary compliance burdens and help ensure that CBI is properly protected.

Further, this section of the regulations should focus on the interrelationship of the new Safer Consumer Products law with existing California laws on trade secrets. California Civil Code § 3426.1 provides:

(d) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one would need to show that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by DTSC under California Health and Safety Code §25257(d) should logically begin by looking at those two questions. While it seems that the gist of each of these two questions is addressed in subpart (a) of the document, subpart (b) requires, by itself, the submission of a large quantity of information, on top of the already large quantity of information that is being requested by the Proposed Regulation. Further, if any of the Trade Secret claims themselves are claimed to be Trade Secret, the entire process of subparts (a) must be submitted as per subpart (b), setting up a potential feedback loop of data submissions to the department. In particular, subparts (a)(4-8) will almost invariably involve trade secret information.

DRAFT – do not cite or distribute

The exclusion of all chemical identity information in subpart (f) is overly broad due to the broad definition of “hazard trait” found in OEHHA’s supporting regulations. For example, a chemical with the hazard trait of “irritation” cannot be claimed as a trade secret, even if it is not being assessed for that trait. Often, chemical identity is the most closely guarded trade secret, and, as drafted, the Proposed Regulation will substantially reduce the ability to protect such intellectual property.

For subpart (g), how does a manufacturer establish a chemical use is a “new use?” Proving that a chemical has never been used is difficult.

#### **Section 69510.1. Department Review of Claims of Trade Secret Protection**

As mentioned in our comments to section 69507, it is not clear why the DTSC would not subject these determinations to an agency review process. We appreciate that the DTSC has included in subpart (d) that the Department may not disclose information until a court proceeding is finished; however we are still concerned with the timelines, in particular subpart (b)(2). It is unlikely that a manufacturer will be able to respond or file an action in 30 days.

#### **Conclusions**

ITI, TechAmerica, CEA and SIA wish to thank the Department for its ongoing work on the Proposed Safer Consumer Product regulation, and feel that the proposed regulations contain several significant improvements compared to previous drafts. However, we are very concerned with the lack of specificity in several sections of the regulations, the immense data submission burdens, the required use of certified assessors, and the very weak trade secret protections offered in the draft regulations. We share the Department’s goals of a meaningful and workable regulation, but unfortunately feel that the proposed regulations contain several sections, as outlined above, that would make these difficult for industry to interpret and meet, as well as for the Department to enforce. We look forward to continuing to work with the DTSC to finalize a workable set of regulations in a manner that will focus on the chemicals and products that pose the greatest risk.

If you have any questions, please do not hesitate to contact Chris Cleet at (202) 626-5759 or [ccleet@itic.org](mailto:ccleet@itic.org), or Robert Callahan at (916) 443-9088 or [robert.callahan@techamerica.org](mailto:robert.callahan@techamerica.org).

Sincerely,

## GCREgs@DTSC

---

**From:** dennis <ddtap@comcast.net>  
**Sent:** Monday, October 01, 2012 7:49 AM  
**To:** GCREgs@DTSC  
**Subject:** consumer labeling

**Categories:** Comment

I would hold up to criminal contempt any public officer who did not complete the job set to him. Complete the list of "chemicals of concern" so that the public may know of them and may avoid them.

Sincerely, Dennis Tapley, 



October 11, 2012

Ms. Debbie Raphael  
Department of Toxic Substances Control  
c/o Krysia Von Burg, Regulations Coordinator ([gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov))  
P.O. Box 806  
Sacramento, CA 95812-0806

RE: Proposed Regulations – Safer Consumer Product Alternatives

Dear Debbie:

Many thanks to you and the entire DTSC team for your long and thoughtful effort to develop the Safer Consumer Product Alternatives Regulations. DTSC has constructed a practical regulatory framework for meaningful implementation of AB 1879 and SB 509. The proposed regulations, which are consistent with scientific advice from DTSC's Green Ribbon Science Panel, have a solid scientific basis.

Although the regulations appear ready to implement, I suggest that DTSC consider the following minor changes to improve DTSC's capability to address non-human environmental problems.

#### **A. Chemicals of Concern – Environmental Toxicants**

One of the challenges in developing these regulations has been identification of scientifically robust lists of chemicals of concern for the non-human environment, since relatively few such lists exist. In consultation with scientists in the water quality community, I have identified two such lists that I recommend DTSC consider adding to Section 69502.2(a). Both lists have an important difference from the lists of water pollutants harmful to aquatic life in the current regulations—these lists better reflect current priorities and both are regularly updated to reflect new scientific information.

1. California's Clean Water Act Section 303(d) list – This is the list of the state's identified water pollution problems. It is updated regularly on the basis of new scientific data. It is a regulatory list based on scientific data that is vetted through public review, Water Board vote, and U.S. EPA approvals. The current version of the list is available from the State Water Board.<sup>1</sup>
2. The European Union's list of Priority Substances under the Water Framework Directive – This is the European Union's list of chemicals that pose the greatest

---

<sup>1</sup> [http://www.waterboards.ca.gov/water\\_issues/programs/tmdl/integrated2010.shtml](http://www.waterboards.ca.gov/water_issues/programs/tmdl/integrated2010.shtml)

threats to water quality. This regulatory list is based on scientific information, is vetted through a public review process, and is adopted by a regulatory agency. It is updated regularly. The current version of this list is in Annex II of the Directive on Environmental Quality Standards (Directive 2008/105/EC).<sup>2</sup>

Both of the above lists meet all of the chemical list criteria specified in the Initial Statement of Reasons.

## **B. Initial Priority Products List**

Most of California's water pollution problems are not associated with the types of pollutants on the lists in Section 69502.2(a)(1), which list human persistent, bioaccumulative toxicants (PBTs) and human carcinogens, mutagens, and reproductive toxicants (CMRs). Using these human pollutant lists to constrain the Initial Priority Products List (Section 69503.3(g)) would prevent the state from tackling important water pollution problems during initial implementation of the regulation.

To ensure that the state can immediately address California's water pollution priorities, DTSC should modify Section 69503.3(g) to add presence of a chemical of concern on the Clean Water Act Section 303(d) list as sufficient basis for selection of an initial priority product. This change would add a small number of pollutants (fewer than a dozen) to the initial eligible list and would ensure that the state's most common non-pesticide chemical water pollution problems (e.g., copper and zinc) can be addressed.

## **C. Regulatory Response Selection**

I commend DTSC's decision to add regulatory response selection principles (Section 69506). This type of guidance has proven invaluable in other regulatory programs.

Two slight modifications of these principles would allow DTSC to better balance non-human environmental protection in its decisions:

- Amend Section 69506(c)(3) to provide for consideration of burdens on all types of organizations. The current list excludes organizations responsible for natural resources, water quality, and wildlife. Examples of the types of organizations that may experience burdens are other government agencies (such as California State Parks, California Water Boards, California Fish & Wildlife, Caltrans, local governments, and municipal wastewater treatment plants) and non-profit organizations (such as non-profit land stewardship and wildlife conservation organizations).
- In addition to sensitive subpopulations, add sensitive ecosystems to Section 69506(c)(4).

---

<sup>2</sup> [http://ec.europa.eu/environment/water/water-dangersub/pri\\_substances.htm#dir\\_prior](http://ec.europa.eu/environment/water/water-dangersub/pri_substances.htm#dir_prior)

On the basis of my experience with agency decisions about other consumer products, I encourage DTSC to add another principle to Section 69506(c) that directs the Department to minimize the time frame required for achieving human and environmental protection.

#### **D. Presentation of Alternatives Assessment Results**

Although Alternatives Assessment should be summarized in a matrix, this should not be the only way that results are presented. The analysis will not be transparent without accompanying text. To address this, I suggest a minor revision to Section 69505.5(f)(1)(B) (page 47 line 14):

“(B) The information required under subparagraph (A) must be ~~presented~~ summarized in a matrix, or other format, that provides the reviewer with an easily understood visual comparison of the chemicals and their adverse impacts.”

#### **Conclusion**

It has been an honor to have the opportunity to serve on the Green Ribbon Science Panel and to assist DTSC with the development of its landmark program to protect human health and the environment from pollutants in consumer products. I would be pleased to continue to provide whatever support I can toward helping you create a practical, meaningful, and scientifically robust regulatory program.

Sincerely,

/s/

Kelly D. Moran, Ph.D.  
President

Test & Measurement Coalition Comments on Proposed  
Safer Consumer Product Regulations of July 2012

**Introduction:**

The Test & Measurement Coalition represents an ad-hoc group of global companies active in producing electronic industrial test and measurement products (including professional and laboratory types) which are classified as Category 9 industrial monitoring and control equipment in the European Union RoHS and RoHS 2 (Recast) Directives. The Coalition includes six leading companies in the sector including Agilent Technologies, Anritsu, Fluke Corporation, Keithley Instruments, National Instruments, and Tektronix. We estimate the Coalition membership represents roughly 60% of the global production of industrial test and measurement products.

The Test & Measurement Coalition has not previously provided comments on informal drafts of the California Safer Consumer Product Regulations as it was not understood to impact the industrial manufactured products sector. We are now compelled to provide our comments on the draft regulations in light of the definition of 'consumer' inherent in the scope of products to be covered by the regulations. The Coalition members are very concerned about the impact the overly-broad definition of the terms 'consumer' and 'consumer product' in the regulations will have on the test and measurement industry and consequently on the competitiveness of downstream customers who require test and measurement equipment to enable innovation in design, quality in manufacturing and accuracy in data acquisition.

The design and qualification process, volume of product placed into commerce, product life, and customer base related to the industrial test and measurement sector are very different than those for typical manufactured consumer products. They cannot be treated in the same fashion as manufactured products which enjoy a much more rapid design and manufacture cycle. Additionally, due to the small volume of product involved, potential impacts to consumer safety from industrial test and measurement equipment in the sector are vanishingly small when compared to the volume of consumer products in the market.

We therefore respectfully request that industrial test and measurement equipment be excluded from the scope of the Safer Consumer Product Regulations as was done for professional medical devices, which have similar design imperatives.

### **General Comments:**

We believe the proposed regulations, as they stand, do not represent the input or concerns of the broad base of small, medium and large enterprises manufacturing industrial test and measurement products which are not typically deemed 'consumer' products under United States law. Products not falling under the aegis of the Consumer Product Safety Commission, such as industrial test and measurement equipment, typically have unique design, qualification and regulatory requirements, smaller volumes of product placed into commerce, longer product life, and a highly trained customer base as compared to those for typical manufactured consumer products.

As such, they should not be treated in the same way as manufactured products which enjoy a much more rapid design and manufacture cycle — a fact that has been acknowledged in the European Union's treatment of industrial test and measurement equipment during the development of the Directives concerning the use of certain hazardous substances in electrical and electronic equipment (RoHS & RoHS 2.) Industrial test and measurement equipment, as part of the industrial monitoring and control category, has been granted the longest transition time — 15 years from publication of the RoHS Directive — to achieve removal of the six original restricted substances. The transition requires this extended timeframe as well as many technical exemptions allowing continued use of the six substances in specific applications which have been granted exclusively for use by the monitoring and control, and medical sectors.

Without such a long transition for the removal of the substances, there is significant risk of forcing premature withdrawal of products that are vital in supporting research and development, manufacturing, and monitoring of core infrastructure required to maintain public or environmental safety (e.g. telecommunications systems, industrial emergency shutdown systems.) Industrial test and measurement equipment typically enjoys a long life and customers may mandate that the same product be available for many years in order to support drop-in replacement in systems that can't be easily redesigned to accommodate new equipment. Unanticipated withdrawal of a product from the California market could be devastating in such circumstances.

Similarly, the same product may move in and out of commerce, sometimes for many years, under leasing arrangements which are necessary for many small and medium enterprises who could not otherwise afford the high price of specialized test and measurement equipment required to support their business needs. If products must be withdrawn from availability for lease due to substance restrictions, there would be significant negative impact on the both the leasing companies and their small and medium-sized clients.

Recalibration, reuse in part or in whole, and refurbishment are also utilized to extend the life of test and measurement equipment and its availability across the spectrum of customers. Inclusion of test and measurement equipment in the scope of the proposed Safer Consumer

Product Regulations puts all these activities at risk with no proportional health or environmental benefit.

It should also be noted that industrial test and measurement equipment manufacturers must spend a disproportionate amount of resources to assure availability of existing product, when compared to the consumer electronics sector, by counteracting the withdrawal of needed components from the supply chain due to the extended longevity of the product's design. This is usually handled by performing a lifetime buy of the component in question or a small-scale redesign to substitute a different component. A natural consequence of this business process is that there will be some number of components for which it will be very difficult, costly or impossible to obtain substance information with no continuing support from the original manufacturer of the part.

Additionally, this diversion of design engineers toward sustaining work means that there are fewer resources available to work on the design of new products or change designs to eliminate substances. Any redirection of design resources toward substance elimination will therefore have a negative impact on innovation in the industrial test and measurement industry and consequently on the competitiveness of downstream customers working to extend performance of their products to the next level. Test and measurement equipment capabilities must stay ahead of the technological curve of the downstream industries in order to support their design work.

For these reasons, as well as the procedural and technical reasons outlined in more general electronics industry commentary provided by various trade associations, we believe the Safer Consumer Product Regulation is not a suitable instrument for regulating substances of concern in industrial test and measurement equipment. We therefore request that industrial test and measurement products be removed from the scope of the regulations as has been done for professional medical devices, which have similar design constraints.

**Specific Comments by Section:**

**Section 69501. Purpose and Applicability**

As noted in the general comments, the regulation should exclude industrial test and measurement products explicitly. We suggest modifying §69501. (b)(2) with an additional sentence as follows:

(2) This chapter does not apply to any product that is exempted from the definition of "consumer product" specified in Health and Safety Code section 25251, or to any product that is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and

Safety Code section 25251. This chapter does not apply to any product that is a manufactured test and measurement product that is not subject to the authority of the Consumer Product Safety Commission.

### **Section 69501.2 Definitions**

The 'Consumer Product' definition requires modification to remove industrial test and measurement equipment from the meaning. We suggest the modification of point §69501.2 (a)(22)(A)1 to align it with the revised text for §69501 (b)(2):

(22)(A) "Consumer product" or "Product" means any of the following:

1. A "consumer product" as defined in Health and Safety Code section 25251; excluding manufactured test and measurement products that are not subject to the authority of the Consumer Product Safety Commission;

### **Conclusions**

The members of the T&M Coalition wish to thank the Department for considering our comments and suggestions regarding these regulations. We are very concerned with the unintended consequences that could arise due to premature withdrawal of industrial test and measurement equipment from California commerce if it were to be subject to the requirements of the Safer Consumer Product Regulations. We therefore respectfully request that industrial test and measurement equipment be removed from the scope of the regulations.

If you have any questions on our submission, please do not hesitate to contact the T&M Coalition for further information.

On behalf of the Coalition,



Martin Baggs  
Tektronix, Inc.



FRANK SCOTTO  
MAYOR

---

# CITY OF TORRANCE

---

October 10, 2012  
SENT VIA U.S. MAIL &  
ELECTRONIC MAIL [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Director Debbie Raphael, DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806

**RE: Comments on Draft Regulations for Safer Consumer Product Alternatives**

Dear Director Raphael:

The City of Torrance, as a proponent of product stewardship, is in support of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from the California Product Stewardship Council (or CPSC, of which Torrance is a member) and local government agencies and the public prior to approving the plan. The CPSC expertise with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs – Add that reducing the cost to municipalities is a priority. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,

Frank Scott  
Mayor, City of Torrance

FS:maw  
cc: City Council Member  
LeRoy Jackson, City Manager  
Robert Beste, Public Works Director  
Alison Sherman, Waste Management Coordinator

**From:** Rory <roaringrory@cox.net>  
**Sent:** Tuesday, October 09, 2012 8:20 AM  
**To:** GCREgs@DTSC  
**Cc:** Rory  
**Subject:** Safer Consumer Product regulations  
  
**Categories:** Comment



TO: Ms. Von Burg,

I am writing you this letter to let you know my concern about the Safer Consumer Product regulations and green products use. If this adoption regulation takes place it may cause many small businesses and even large businesses to suffer financially. Please be cautious in adopting these new regulations.

Thank you.

Rory Townsley



**FREE Animations for your email** [Click Here!](#)





October 11, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Subject: Comments on the California Department of Toxic Substances Control – Proposed Regulation: Safer Consumer Product Alternatives**

Dear Ms. Von Burg:

Below please find a summary and detailed discussion of key concerns from the Toy Industry Association (TIA) regarding the Department of Toxic Substances Control (DTSC or Department) Proposed Regulations for Safer Consumer Product Alternatives (Proposed Regulations) under Assembly Bill 1879 and Senate Bill 509 (2008). We remain concerned about the current structure and requirements of this proposed regulation and believe that the current draft is unworkable.

TIA is disappointed to find that these regulations lack the transparency and predictability necessary to both operate and achieve the goals of a program of this magnitude, and would appreciate the opportunity to work with DTSC staff to make changes that will yield a truly workable regulatory program. TIA strongly believes that with significant and substantive redrafting of these regulations, it is possible to create a regulatory proposal that protects human and environmental health, without catastrophic effects on commerce and product innovation.

These comments are in addition to, and incorporate where relevant, previous comments submitted to the Department by TIA on July 20, 2010, November 1, 2010, December 3, 2010, December 30, 2011 and May 30, 2012. TIA continues to urge the Department to seriously consider compromise and progress toward reaching a workable solution that is consistent with other states, as it is difficult for our industry to see a path forward toward workable Green Chemistry Regulations without consistency between states on key issues.

TIA is a not-for-profit trade association representing more than five-hundred (500) toy makers, marketers and distributors, large and small, located throughout North America. TIA's members account for approximately 85% of the annual U.S. domestic toy market of \$21.6 billion, according to research from the NPD Group. Additionally, Toy Industry Association members employ more than 32,000 employees in California with a direct economic impact of more than

\$6 billion to the state. The Toy Industry Association and its members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S. risk-based standards are widely recognized and used as models around the globe. One of our missions is to educate industry on these standards, and to educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

Below are fundamental concerns with the proposed Rule that TIA believes must be addressed before a workable regulation can be adopted:

**It is imperative that DTSC take the most effective and least burdensome approach to meeting its mandate to adopt regulations.** Addressing the following issues would create a more effective and workable program, while minimizing the burden these regulations will place on the California and national economies:

- **Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2]:** As DTSC acknowledges in their “Initial Statement of Reasons” (ISOR) [Section 69503.2], there is little to no exposure to a “Chemical of Concern” (CoC) from inaccessible components. In order to provide appropriate focus to the prioritization process, there is a need to define “inaccessible components” and remove these components from prioritization. This approach is consistent with California’s statute – § 25252(a) of the statute directs DTSC to consider potential exposure and exposure pathways which supports the exclusion of inaccessible components from coverage by the regulation. It is also consistent with similar laws regulating the presence of chemicals in children’s products in Washington State, Maine and on the federal level under the Federal Hazardous Substances Act and the Consumer Product Safety Improvement Act.

*TIA proposes adding new language in Section 69503.2 stating that “The Department shall not consider the presence of a chemical of high concern which is solely contained within inaccessible components as a basis for naming or selecting a priority product, unless the Department finds scientifically credible, peer-reviewed data indicating that significant adverse impacts to human health or the environment have resulted from exposure to inaccessible components at any time during the life cycle of the product.”*

We further suggest that if a definition of “inaccessible” is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

- **Link Between Priority Products and Potential Exposure [Section §69503.2]:** When determining priority products, it is critical that DTSC demonstrate both an exposure pathway AND that the pathway for a product is a significant contributor to a

cited human and/or environmental exposure. Products that are a minimal contributor to exposure should not be listed as a “Priority Product.”

Currently, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include “reliable information regarding exposures.” The ISOR states relevant information may include monitoring data, environmental media data and biomonitoring data. What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. TIA is interested to know on what basis DTSC determines that a specific product is a significant contributor to the pollution or bioburden, or even that it contributes at all? The current stance of the Department places the burden of proof (to prove a negative) on those being regulated, rather than the Department having a duty to establish with a reasonable degree of certainty that a specific product is a significant contributor to the exposure.

Additionally, the Regulations give consideration to “Intended product use(s)” [Section 69503.2]. However, when determining priority products based upon exposure, it is essential that the Regulations specifically stipulate that the exposure evaluations apply to “reasonably foreseeable” exposures from a product during reasonably foreseeable processing, use, and end-of-life management for the product. An understanding of “real world” concentrations, routes of exposure, and existing mechanisms to prevent harm must be built into these Regulations.

- **Intent/Definition of “Highly Durable Products” [Section §69503.4]:** After discussions with DTSC staff, it is clear that what was intended here is to denote a class of products which are “complex” rather than “highly durable” in order to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is arbitrary and capricious to summarily discriminate against children’s product makers by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children’s products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.
- **Alternatives Assessment (AA) Threshold Exemption [§69503.5]:** The overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department and manufacturers will be overwhelmed by unnecessary paperwork under this provision, and consumers will be overwhelmed with information that is likely to be confusing and misleading. The process requires the release of proprietary

data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it has a Priority Product that contains a Chemical of Concern below the AA threshold level. The Department could then request additional information if needed. Notifying entities should be allowed to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

**DTSC should develop a transparent and predictable regulatory framework in order to establish an effective and workable program.** The narrative, rather than prescriptive, approach in these regulations creates an enormous burden of ambiguity and uncertainty for those required to comply, in order to provide DTSC with “maximum latitude and flexibility.” **It is a basic tenet of good regulation that those being regulated must understand what is being regulated and be able to predict the effect of that regulation on their products; in this the Department has so far been unsuccessful.** Addressing the following concerns would help to achieve the transparency and predictability needed for a workable program:

- **Regulatory Duplication Applicability [Section §69501]:** Per the mandates of AB 1879, products where another federal or California State regulation addresses the same risk of injury or environmental threat that has resulted in DTSC prioritizing a chemical or product, must be excluded from further duplicative regulation. Unfortunately, DTSC deleted this exclusion from the “Purpose and Applicability” section (per the October 2011 draft). Regulatory duplication is given consideration during the product prioritization process under the current proposal. However the exclusion must be maintained from the onset of the regulations, not just as a product prioritization factor.

In addition, this concept must be carried through consistently throughout the regulations, including the requirement of Alternatives Analysis (AA) and regulatory response considerations in the AA. If an AA has been completed or is in progress under another state’s regulatory program, then the Department should not require an additional AA, but rather require supplemental information, if necessary. If end-of-life management is already regulated in California, or by the federal government, it is duplicative to include such management in a regulatory response required under this Chapter. The Department should acknowledge that certain other regulatory programs, combined with this Chapter, will provide complete life cycle management of the exposure risks for Chemicals of Concern (CoC) in Priority Products in California.

- **Define Contaminant & Intentionally-Added [Section §69501.1]:** As “contaminant” is referenced in Section 69503.5 of the proposed regulations and is a recurring concept in the ISOR, these regulations should provide a clear definition of contaminant and, in contrast, intentionally-added chemicals. Additionally, whether a chemical is an intentionally-added ingredient or a trace contaminant should impact how an AA threshold is established. Specifically, in a manner that is consistent with Washington State, a trace contaminant or an unintentionally added chemical should be considered differently in setting the AA threshold level.
- **Alternatives Analysis Threshold [Sections §69503.5]:** The Regulations do not provide a clear and predictable process for how AA threshold levels will be determined. Instead, the Regulations provide that the Department may raise or lower a previously established AA threshold level, which creates future uncertainty. TIA believes it is critical to have predictability, and urges DTSC to consider approaches consistent with Washington State and Maine that set clear threshold levels and consider whether a chemical is intentionally-added or is a contaminant in setting the AA threshold level. Additionally, the Regulations do not address whether an unintentionally-added ingredient or a trace contaminant impact AA threshold.
- **Alternatives Analysis [Article 5]:** Alternatives assessment is core to developing safe consumer products and TIA supports a pragmatic and science-based approach. TIA believes the AA Industry Coalition’s “Product development and improvement paradigm” (submitted to DTSC on October 8, 2012) is a solid basis for an appropriate framework. TIA shares the concerns noted in the comments from the European Union (EU) that requirements in the draft Regulations for conducting an AA are highly complex, both technically/content-wise and administratively, and DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate.
- **Trade-Related Issues [Articles 8 & 10]:** The Regulations as currently drafted have the potential to negatively impact trade. As noted in the comments from EU a proper economic analysis has not been completed on these regulations as was conducted by the EU, at the request of the United States and others, before REACH was adopted. The EU comments also point to potential issues with Article 8 setting up a highly unique accreditation and certification scheme that is not recognized beyond State boundaries. TIA shares these concerns, and recommends accreditation by an International Laboratory Accreditation Cooperation (ILAC) – Multilateral Recognition Arrangement (MLA) signatory which is accredited to ISO 17021 be sufficient for the certification of assessors.
- **Confidential Business Information [Article 10]:** Additionally, since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected (Article 10). The nature of the data required to be submitted - once a priority product and chemical

concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. Moreover, Confidential Business Information, which may not fall within the definition of “trade secrets,” should also be protected.

In addition to the key issues noted above, we present in this letter a section-by-section analysis of specific elements within the Proposed Regulations that are problematic. TIA hopes that these comments are helpful to the DTSC as the regulations continue to be revised.

## Section Comments

### **Section 69501.1 Definitions**

**“Accessible Component”** – For assembled products there is a need to define “accessible components”; which also should be referenced in several key places in the regulation to properly focus these regulations and resulting compliance requirements on those components for which there is a likelihood of exposure. Both the terms accessible and inaccessible component are critical to focusing these regulations on actual potential for exposure.

**“Adverse Ecological Impact”** – This definition contains several subjective terms that lack standards and clear definition for determining an actual adverse impact. Specifically, “Deterioration or loss of environmentally sensitive habitats” and “changes in ecological communities” are terms that lack clear definition and exposition regarding how the DTSC will evaluate these impacts.

**“Contaminant”** - There is a need to define “contaminants”; which is referenced in Section 69503.5 (c)(1)(A) & (C) of the proposed regulations, and is a recurring concept in the ISOR. TIA recommends the following definition; which is identical to Washington State’s WAC 173-334-040:

***"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.***

**“Homogenous Material”** – This term is difficult to define and has been problematic in the EU RoHS Directive. Therefore, we suggest removing the definition of “Homogenous Material” from the regulations. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but this can be addressed in the definitions of “component” and “consumer product.” TIA recommends the following definitions:

***(21) “Component” means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:***  
***(A) Is required to complete or finish an item***

***(B) Performs a distinctive or necessary function in the operation of a product or part of a product***

***(C) Is intended to be included as a part of a finished item***

***(22)(A) “Consumer product” or “Product” means any of the following:***

***1. A “consumer product” as defined in Health and Safety Code section 25251;***

***2. A component, or uniquely identifiable material within a component, that is identified under section 69503.4(a) (2) (B), as the minimum required focus of an AA.***

**“Inaccessible component”** – For assembled products there is a need to define “inaccessible components”; which also should be referenced in several key places in the regulation to prevent the regulations from overreaching and focusing on components where there is no reasonable likelihood of exposure. We further suggest that if a definition of “inaccessible” is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

**“Intentionally-added chemical”** - There is a need to define “intentionally-added chemicals.” TIA recommends the following definition; which is identical to Washington State’s WAC 173-334-040:

***"Intentionally added chemical" means a chemical in a product that serves an intended function in the product.***

#### **Article 1, Section 69501.5 – Availability of Information on the Department’s Website**

**AA Threshold Exemption Notification** – As stipulated above and below, to require companies to submit the current proposed AA threshold exemption is unworkable both for the reporter’s and Department’s workload and it is not necessary for the stated purpose of advising DTSC. The sole purpose in creating a threshold is because it has been determined that a Chemical of Concern below that level does not pose a concern to human health or the environment and should not be prioritized. Further, notification of the fact that a company has provided a threshold exemption, in the eyes of the public, would equate to a black list of products and would require disclosure of potentially confidential information, with no public benefit. Of greater concern is that competitors could glean confidential business information from such reports; thus, chemical identity must be allowed to be kept confidential in such cases

#### **Article 2, Section 69502.2 – Chemicals of Concern Identification**

**(a) Initial Chemicals of Concern List and (b) Additions to the Chemicals of Concern List** – The inclusion of such a broad list of chemicals of concern (CoC), that is estimated to contain 1,200 chemicals, does not provide predictability and certainty to companies. There must be a clear safety-based approach to prioritizing chemicals of concern within these regulations. This is the basis of international chemical regulations; such as the European Union REACH process and the Canadian Domestic Substances List program. Additionally, states like Maine and Washington State have adopted step-wise processes for prioritizing chemicals. While all

stakeholders may not agree on the chemicals selected at each prioritization step, this process is necessary to providing predictability and direction to the market-place. Finally, Alternative Assessments must not fall into the same trap, a rigid prohibition on replacing a CoC with anything on a list, but instead take a more holistic approach - that any proposed alternative must on balance improve the safety and environmental profile of the product.

**(b)(4) Safer Alternative** – It is not reasonable to suggest that any chemical that has a “safer alternative” should be considered a CoC. Any chemical that is added to a CoC list must demonstrate a realistic potential for exposure and adverse impacts to human health or the environment. For example, purified water might be considered to be “safer” than tap water from a municipal supply, by some extremely tiny margin. However, such justification does NOT prove that tap water should be considered a CoC. In addition, exposure under real-world conditions of use must be considered: if a chemical can potentially be replaced with another exhibiting lower hazard, but such substitution (due to reduced performance or other factors) results in a greater exposure, this may not be the desired outcome.

### **Article 3. Chemicals of Concern and Consumer Product Prioritization Process**

**Section 69503.1. Applicability** – The applicability section should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Per the comments above, reasonable and foreseeable exposure through normal use and abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. As discussed above, the U.S. Consumer Product Safety Commission (CPSC), in August 2009, once again endorsed the reasonable and foreseeable exposure criterion in regulation through the “Children’s Products Containing Lead; Interpretative Regulations on Inaccessible Component Parts” (16 CFR Part 1500).

**Section 69503.2. Priority Product Prioritization** – This section should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Per the comments above, reasonable and foreseeable exposure through normal use and abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. Assembled products that only contain CoCs in inaccessible components - for which there is no reasonable and foreseeable exposure pathway - should not be prioritized under this section. Only accessible components of assembled products should be the focus of these regulations; since they are the only reasonable and foreseeable components with the potential for exposure. The principle of applying chemical regulations only to accessible components of assembled products has been validated by the U.S. Consumer Product Safety Commission (CPSC), the Maine Department of Environmental Protection (DEP), and Washington State DoE under substantially similar laws. CPSC regulations – 16 CFR, Part 1500.48 and 1500.49 – can provide guidance for DTSC regarding specific technical requirements for determining accessibility

Additionally, the Department does not have regulatory authority under this statute over workplace exposures to CoCs; especially if those exposures occur beyond California’s boundaries. Workplace exposures are the jurisdiction of U.S. OSHA and Cal OSHA. Thus these “manufacturing” exposure considerations should be removed from this Section.

#### **Section 69503.4. Priority Products List**

**(a)(2) Highly Durable Products** – As discussed above, “Highly Durable Products” should be changed to more closely reflect DTSC’s intent. After discussions with DTSC staff, it is clear that what was intended here is to denote a class of products which are “complex” rather than “highly durable” in order to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is *arbitrary and capricious to summarily discriminate against children’s product makers* by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children’s products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

**Section 69503.5. Alternatives Analysis Threshold Exemption** – As outline above, the regulations do not provide a clear and predictable process for how AA threshold levels will be determined. Instead, the regulations provide that the Department may raise or lower a previously established AA threshold level, which creates future uncertainty. Additionally, the regulations do not address whether an unintentionally-added ingredient or a trace contaminant impact AA threshold. Once again, TIA urges DTSC to consider approaches consistent with Washington State and Maine – the regulations should set clear threshold levels and consider whether a chemical is intentionally-added or is a contaminant in setting the AA threshold level. We recommend the following structure:

- A. For a chemical that is an intentionally added chemical in an accessible component of a product, the practical quantification limit; or*
- B. For a Chemical of Concern Priority Product combination in which the chemical of concern is a contaminant present in an accessible component of a product, a concentration of 100 parts per million; or*
- C. Any concentration in a product, if that chemical occurs only in an inaccessible component or occurs in a product only as a contaminant, as long as the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.*

**Section 69503.6 Alternatives Analysis Threshold Exemption Notifications** – As discussed above, the overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department will be overwhelmed by unnecessary paperwork under this provision and consumers will be overwhelmed with information that may be confusing and misleading. The process requires the release of proprietary data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it has a Priority Product that contains a Priority Chemical below the AA threshold level and allow such notifying entities to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. The Department could then request additional information if needed. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

**Article 5: Alternatives Assessment** – The alternatives assessment process is essential for developing safe and innovative children’s products. The fundamentals of the process are routinely executed as part of industry’s ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs, expectations, and preferences, is the ability for manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives assessment.

Alternatives assessments may be undertaken by individual manufacturers, or by consortia representing an industry segment or an entire industry. Due consideration to safety, complexity (different factors are relevant to a specific chemical/product/use combination, and must be evaluated on a case-by-case basis), effectiveness, lifecycle thinking, consumer acceptance, cost to consumers, manufacturability, and informed decision-making (weighing trade-offs) will ensure a workable, practical, and meaningful Green Chemistry program in California. The most appropriate alternative for a particular product would be selected by the product manufacturer to ensure that it fits well within their unique business model.

A rational, structured and predictable alternatives assessment process is essential from a business perspective and TIA supports the Green Chemistry AA Coalition’s “Product development and improvement paradigm” as an appropriate framework.

Beyond these necessary factors for an Alternatives Assessment, TIA is concerned that as drafted DTSC would make the proprietary work and knowledge that a company must perform to complete an Alternative Assessment report publically available. We believe that by making a company’s Alternative Assessment report, and their conclusions, public (even if the report is redacted) would jeopardize a company’s ability to protect certain information as confidential business information (CBI).

**Article 8. Accreditation Bodies and Certified Assessors** – The use of certified AA assessors is an acceptable concept, but “certified” should not be read exclusively as “third-party”; the use of in-house assessors should be expressly permitted by regulation. Assessors should also not be required to be technically expert at all aspects of an AA, but should instead be expected to be capable of managing the AA process to be certain that all applicable parameters are considered.

In-house company experts (product development engineers and others within a company with product development responsibility) with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead alternative assessment projects for product development and should not have to become certified assessors, or should be certified with minimal requirements based on their experience.

As stated above, the comments submitted by EU point to potential issues with setting up a highly unique accreditation and certification scheme that is not recognized beyond State boundaries. TIA shares these concerns, and recommends accreditation by an ISO 17021-accredited International Laboratory Accreditation Cooperation (ILAC) – Multilateral Recognition Arrangement (MLA) signatory be sufficient for the certification of assessors. Additionally, the process of certification should be such that certification is readily achievable by product development professionals with relevant experience and education. This approach would be in keeping with previous California precedent; when “Quality Engineer” was added to the state’s categories of engineering technology for which state licensing is available, already-practicing quality engineers with a minimum level of specified experience and/or education were “grandfathered” and granted a license without a licensing examination. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors’ work products) that is being certified. DTSC should have the ability to challenge the Accreditation body.

#### **Article 10. Trade Secret Protection**

Since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected. The nature of the data required to be submitted - once a priority product and chemical concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. It is a major concern to TIA that Confidential Business Information (CBI), may not fall within the definition of “trade secrets.” We recommend the following changes:

- A. Add to definition section, Confidential Business Information: *Any information in the custody of a business entity that the business entity reasonably expects to be preserved as confidential in order that the business may obtain or retain business advantage from its rights in the information.***
  
- B. Add a section to the Trade Secrets Provision: *In addition to trade secrets, a claim for Confidential Business Information will be reviewed by the Department to determine if disclosure of such information would cause substantial harmful effects to the claimant, including revealing capital and marketing costs, specialized technical expertise, unusual processes, or unique ingredients, or give competitors access to customers or information that may give them a competitive advantage. The claim shall include details of the substantial harmful effects to claimant, as well as a redacted form of the information.***

Additionally, the Department’s interpretation of statute that “chemical identity” is not considered a trade secret is problematic. Disclosure of a chemical’s identity often provides the ability for

competitors to determine trade secrets such as the raw materials being used in a product, or the process by which a product is made. Even if §25257(f) were interpreted as DTSC desires to mean that trade secret protection does not attach to hazard trait information, proposed §69510(f) still exceeds the scope of the statute. The proposed regulation does not merely ban trade secrecy protection for hazard trait submission information; it also eliminates trade secret protection for “any chemical identity information associated with a hazard trait submission.” However, §25257(f) does state that it does not apply to chemical identity information associated with a submission, just that it does not apply to “hazardous [sic] trait submissions.”

The problem with the Department’s interpretation of §25257(f) is that its interpretation fails to differentiate between “hazard traits,” which are specific hazards, such as corrosivity or ignitability, and “chemical identities,” which are a separate type of information different than hazard traits. It would be unreasonable to interpret §25257(f) as preventing persons from claiming trade secret protection for chemical identity information, because disclosure of a chemical’s identity often provides the ability for competitors to determine trade secrets such as the raw materials being used in a product, or the process by which a product is made. What §25257(f) speaks to are specific hazards, not chemical identity. A generic name for a specific chemical is acceptable as long as its specific hazard traits are disclosed. Section 69510(f) must therefore be eliminated, particularly its provision that does not allow companies to claim trade secrecy protection for chemical identity information.

**Conclusion:**

Product safety is a vital consideration for toy manufacturers. A core practice of our industry is to perform rigorous safety-based assessments for all products prior to the marketing of a product and take into consideration potential impacts on children. In addition to meeting stringent internal product safety requirements, toys currently comply with numerous federal and international environmental and safety regulations under a variety of laws and regulations.

TIA appreciates the hard work that has gone into the development of these Proposed Regulations and attempts to balance many stakeholder interests. TIA asserts that the current framework is critically flawed, and significant revisions are needed before this regulation can be considered workable.

Once again, TIA remains committed to working to ensure that these Regulations provide a workable solution to chemicals management issues in California and looks forward to continuing to work with you on these outstanding issues. Please feel free to contact TIA directly via Jennifer Gibbons at: [jgibbons@toyassociation.org](mailto:jgibbons@toyassociation.org) if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully,



Jennifer Gibbons  
Director of State Government Affairs

TIA Comments  
Proposed Regulation for Safer Consumer Products  
October 11, 2012

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



**Tri-iso Inc.**

2187 New Castle Avenue, Suite 101, Cardiff by the Sea, CA 92007 • Tel: (909) 626-4855 • Fax: (909) 621-9119

---

October 2, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of Tri-iso, Inc., I respectfully submit the following comments relative to the Department of Toxics Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

Tri-iso is a U.S. West Coast distributor of specialty chemical raw materials. Tri-iso was founded in the late 1970's. Comprising a group of 25 employees and affiliates, Tri-iso offers extensive technical support and customer service for the products we represent. Our primary goal is to add innovative new products to our portfolio which meet our customer's performance, cost and environmental needs.

On a personal note, I take my personal, my families, my states and my nation's environmental needs very serious. I have put my money where my mouth is as I have driven a hybrid (electric and gas) vehicle for the last 3 years; I live off the grid and generate my households electrical needs via solar energy. My children and I are at the beach and usually in the water on a daily basis and we see the damage that is created from the lack of proper care for our environment and oceans. We regularly take part in organized and unorganized beach clean-ups.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

However, there are many issues that we see RE: sections 69501-69510.1 (b)(2)(c)(d) as well as a few of the bullet points mentioned below.

- We remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to



**Tri-iso Inc.**

2187 New Castle Avenue, Suite 101, Cardiff by the Sea, CA 92007 • Tel: (909) 626-4855 • Fax: (909) 621-9119

---

oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

- Most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.
- It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on **exposure** and **hazard**, and it must avoid duplication and conflicting regulatory requirements.
  - DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
  - GCA supports this two-step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of***



**Tri-iso Inc.**

2187 New Castle Avenue, Suite 101, Cardiff by the Sea, CA 92007 • Tel: (909) 626-4855 • Fax: (909) 621-9119

---

***these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.
- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

My last request, since you may consider Tri-iso and or me to be bias group, at the very least please give serious consideration to the recommendations made by The EU's Giuseppe Casella via email on Sept 11<sup>th</sup> titled G/TBT/NUSA/727. I believe we can consider Mr. Casella to be a neutral third party RE: DTSC.

We appreciate your consideration of our concerns. For further information or questions, please contact Jason Scott at 909/626-4855.

Sincerely,

A handwritten signature in black ink, appearing to be "Jason Scott", written over a light green rectangular background.

Jason Scott  
President/CEO

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



Terrie L. Mitchell  
*Tri-TAC Chair*  
Sacramento Regional County Sanitation District  
10060 Goethe Road  
Sacramento, CA 95827  
(916) 876-6092  
[mitchellt@sacsewer.com](mailto:mitchellt@sacsewer.com)

October 9, 2012

Kryisia Von Burg  
Regulations Coordinator  
Department of Toxic Substances Control (DTSC)  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Green Chemistry Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

On behalf of Tri-TAC, thank you for the opportunity to comment on the Proposed Safer Consumer Products Regulations (proposed regulations). We commend you and the DTSC staff for their systematic, science-based efforts to develop a robust process to improve product safety.

Tri-TAC is jointly sponsored by the California Water Environment Association, the League of California Cities, and the California Association of Sanitation Agencies. The constituency base for Tri-TAC collects, treats and reclaims more than 2 billion gallons of wastewater each day and serves most of the sewered population of California. Wastewater agencies must meet increasingly strict regulatory standards to protect our water resources for a broad array of beneficial uses. We take our responsibilities for safeguarding receiving waters seriously and are very concerned about discharges of certain chemicals into wastewater systems. The growing tide of unregulated chemicals has the potential to compromise effluent quality, biosolids management options, and compliance with National Pollution Discharge Elimination System (NPDES) permit requirements.

### **Support for Proposed Regulations**

Tri-TAC generally supports the concept of green chemistry and these proposed regulations, which have a solid scientific foundation and practical framework. We believe that in time, these regulations will help reduce harmful chemicals in consumer products and thereby assist wastewater treatment agencies in protecting receiving waters. In particular, we appreciate DTSC's efforts to include consideration of adverse impacts to wastewater treatment processes, water quality and aquatic life.

While Tri-TAC supports the proposed regulations and urges DTSC to move forward with them, we also have some suggestions for improvement, which are detailed below, that would strengthen the proposed regulations and have a beneficial impact on water quality.

#### *Vice Chair*

**Jacqueline Kepke**  
East Bay Municipal Utility  
District  
375 – 11<sup>th</sup> Street, MS702  
Oakland, CA 94607  
(510) 287-1608  
[jkepke@ebmud.com](mailto:jkepke@ebmud.com)

#### *Water Committee Co-Chairs*

**Shannon Bishop**  
Los Angeles County  
Sanitation Districts  
1955 Workman Mill Road  
Whittier, CA 90601  
(562) 908-4288 x2843  
[sbishop@lacsdsd.org](mailto:sbishop@lacsdsd.org)

**Jason Lofton**  
Sacramento Regional County  
Sanitation District  
10060 Goethe Road  
Sacramento, CA 95827  
(916) 876-6008  
[loftonj@sacsewer.com](mailto:loftonj@sacsewer.com)

#### *Land Committee Co-Chairs*

**Vincent De Lange**  
East Bay Municipal Utility  
District  
375 – 11<sup>th</sup> Street, MS702  
Oakland, CA 94607  
(510) 287-1141  
[vdelange@ebmud.com](mailto:vdelange@ebmud.com)

**Tom Meregillano**  
Orange County Sanitation  
District  
10844 Ellis Avenue  
Fountain Valley, CA 92708  
(714) 593-7457  
[tmeregillano@ocscsd.com](mailto:tmeregillano@ocscsd.com)

### **Incorporate Water Boards' Highest Priority Water Pollutants – 303(d) List**

Tri-TAC is pleased that the Proposed Regulations define “adverse water quality impacts” to include introduction or increases in pollutants that impair water bodies listed under section 303(d) of the federal Clean Water Act (p. 7, line 6). However, in the section “Chemicals of Concern Identification,” only pollutants listed under section 303(c) of the Clean Water Act are included (p. 22, line 35). A different list, developed by the Water Boards every few years under Section 303(d) of the Clean Water Act, lays out the state’s priority water pollution problems. This is the list of California’s most important water pollution problems. The 303(d) list meets all of DTSC’s stated criteria for inclusion among the lists of chemicals of concern and will help ensure that the most relevant pollutants from a water quality standpoint are considered as chemicals of concern are selected. We request that DTSC include 303(d) pollutants in Chemicals of Concern Identification.

While there is significant overlap between pollutants in section 303(c) and pollutants that have resulted in 303(d) impairments, there are some important differences in how these lists are developed. Water bodies may be deemed impaired under section 303(d) for virtually any pollutant, not just those listed under 303(c). The section 303(c) pollutant list does not change frequently and does not necessarily reflect pollutants affecting California waters. Including both 303(c) pollutants and the 303(d) pollutants in the “Chemicals of Concern Identification” will ensure that the highest priority water pollution problems in the state are addressed.

### **Incorporate High Priority Environmental Pollutants in Initial Priority Products List**

Tri-TAC understands that the proposed regulations must prioritize the vast number of consumer products; however, we are concerned that only products linked to human health concerns will be included in the initial Priority Products List. As currently proposed, the regulations do not allow DTSC to prioritize products containing chemicals that do not impact human health but may have environmental impacts. There are products, like copper-containing vehicle brake pads, that do not directly adversely impact human health, but may have significant impacts on water quality and the environment. We urge DTSC to consider incorporating the 303(c) and 303(d) pollutants into §69503.3. Possible language may be added as follows to p. 29, line 12:

- 12 (3) The chemical is identified as a priority toxic pollutant for California under section 303(c) of the federal Clean Water Act or is a pollutant that has been identified as a cause of impairment of one or more water bodies in California under Section 303(d) of the federal Clean Water Act.

### **Increase Transparency**

Alternatives Assessments. While we understand that DTSC wants to expedite the Alternatives Assessment (AA) process, Tri-TAC believes the proposed regulations should include a formal comment period on preliminary AAs and any revisions to work plans. A formal comment period provides greater transparency, ensures higher quality AAs, and leads to better results since stakeholders may provide insights that may be

overlooked by both certified assessors and DTSC staff. In addition, a formal comment period will provide necessary transparency given that Certified Alternatives Assessors may be employees of the same companies required to conduct an AA.

Invite Public Comment on Product Stewardship Plans. Tri-TAC believes that proposed Product Stewardship Plans for end-of-life management of products should be posted to the DTSC website and DTSC should invite public comment prior to approval of the plans.

Publish All Comments & Correspondence on Website. We also urge DTSC to incorporate language into the regulations (in §69501.5) that requires all notices, public comments, and correspondence with stakeholders to be published on the DTSC website.

### **Consider Costs Incurred by Other Types of Entities**

Wastewater agencies may be heavily impacted by chemicals in consumer products. Consumer products may contain chemicals in quantities that would lead to exceedances of effluent limitations at POTWs and/or water quality objectives in the State's waters. For example, if a chemical enters a municipal wastewater treatment plant in sufficient quantities, it is possible it could harm the crucial microorganisms used to treat wastewater, causing "process interference," or a plant "upset" where wastewater is no longer able to be treated properly before discharge. Process interference and upsets can result in costly NPDES permit violations. In addition, when surface water bodies become impaired by pollutants, wastewater agencies may be subject to additional requirements established as part of Total Maximum Daily Loads (TMDLs). The cost to wastewater facilities and other dischargers to comply with effluent limits and TMDLs can be millions of dollars. In some cases, treatment plant upgrades may be necessary to comply with TMDLs, at enormous cost to the public served by the treatment facility.

To address this, Tri-TAC encourages DTSC to make two changes:

- (1) add language to the Regulatory Response Selection Principles in §69506 (p.52, lines 17-26) so that costs and other burdens (§69506 (a) (4)) incurred by wastewater agencies are considered when selecting a regulatory response.
- (2) add language to provide explicit direction for DTSC to consider these costs as one of the product prioritization factors (§69503.2).

### **Incorporate Exposure Pathways Information in Preliminary Alternatives Assessments**

Tri-TAC appreciates that the proposed regulations require an assessment of exposure pathways from a Chemical of Concern in a Priority Product. However, we believe that the responsible entity should provide this information in the First Stage of the AA, rather than in the Second Stage. Early identification of exposure pathways is important so that any inadvertent omissions or inaccuracies can be addressed at the beginning of the AA process. In our experience with pesticide regulatory processes, certain exposure pathways are often inadvertently overlooked by manufacturers and regulatory entities.

If DTSC incorporates our comment above to invite public comment on Preliminary AAs, then any omitted exposure pathways can be identified by interested stakeholders.

**Consider Other “Unique Burdens”**

We urge DTSC to consider other “unique burdens” in its regulatory responses, and propose modification of §69506 (p.52, lines 24-25) as follows:

- (4) Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations, environmentally sensitive habitats, endangered and threatened species listed by the California Department of Fish and Game, and environments in California that have been listed as impaired by the State or any federal regulatory agency.

Once again, Tri-TAC would like to commend DTSC’s efforts in developing these proposed regulations. With our suggested changes, we believe these regulations will help prevent pollution at the source and will better enable municipal wastewater agencies to meet their obligations to protect water quality and human health. Timely and robust implementation of these regulations is critical – without it, we expect that water quality problems that can only be solved by product reformulation will continue to require legislative solutions on a case-by-case, product-by-product basis, which is inefficient and politicizes the issues. California needs strong Safer Consumer Products Regulations that address problematic hazardous chemicals in consumer products, and that promote the creation and use of non-hazardous alternatives.

Thank you for your consideration of our comments. We look forward to participating in the process of advancing green chemistry and safer consumer products in California.

Sincerely,



Jacqueline Kepke, P.E.  
Tri-TAC Vice-Chair

October 10, 2012

**Via Email (draphael@dtsc.ca.gov)**  
**and Via Federal Express**

Ms. Debbie Raphael  
Director  
California Department of Toxic Substances Control  
1001 "I" Street  
Sacramento, California 95812

**Re: Comments of the Truck and Engine Manufacturers Association**  
**on the DTSC's Proposed Safer Consumer Product Regulations**

Dear Ms. Raphael:

Through this correspondence, the Truck and Engine Manufacturer's Association ("EMA") is submitting its initial comments regarding the proposed Safer Consumer Products Regulations ("Regulations") that the Department of Toxic Substances Control ("DTSC") released for public review and comment on July 27, 2012. EMA appreciates the opportunity to submit these comments, and we look forward to working with DTSC staff to ensure that the DTSC adopts Regulations that are lawful, feasible and cost-effective. As it stands now, the proposed Regulations do not satisfy those necessary criteria.

EMA is the trade association that represents the world's leading manufacturers of commercial engines, equipment and vehicles, other than passenger cars and airplanes. The products manufactured by EMA's members cover the full spectrum of engine and vehicle applications that power our national economy, and include non-hand-held lawn and garden equipment; heavy-duty construction equipment, such as bulldozers, earth-movers and cranes; agricultural machinery such as combines, tractors and sprayers; locomotive and marine engine power systems; on-highway trucks, buses and delivery vans; and stationary engines, including generators, drilling rigs, pumps, and emergency backup power systems. All of those products and more could be deemed to be consumer products - - more specifically, "highly durable products" - - under the draft Regulations sweeping definitions, and so could fall under the four-step program that DTSC has proposed to promote the development and utilization of safer consumer products. EMA regularly represents its members' interests in responding to federal and state regulatory initiatives that impact the engine and vehicle industry, and so has a direct interest in the Regulations at issue.

EMA supports the general intent of the underlying green chemistry statutes (AB 1789 and SB 509), which is to reduce the potential adverse health impacts from consumer products based on a transparent, easy-to-use and cost-effective regulatory process that does not conflict with, supercede or duplicate the regulatory programs of any other state, federal or international

agencies. EMA also acknowledges that such a cost-effective and easy-to-use green chemistry program might be implementable in the context of relatively simple consumer products, such as nail polish, children's toys or fireworks. However, that is simply not the case in the context of the very complex highly durable goods that are manufactured and assembled by EMA's members. To the contrary, and as detailed below, the proposed Regulations are fundamentally unworkable and infeasible in that context.

EMA is a member of the Complex Durable Goods Coalition ("Coalition") and fully endorses and incorporates by reference the comments that the Coalition is submitting. EMA's separate comments will highlight the additional issues and concerns that stem from the fact that the engine, vehicle and power equipment industries already are heavily regulated by federal and state agencies to ensure state-of-the-art emissions control and safety. Thus, the proposed Regulations are likely to create unlawful duplication and conflict with existing comprehensive regulatory programs. DTSC must address this threshold issue through appropriate exemptions and "off-ramps" before finalizing the proposed Regulations. EMA's comments also will discuss the inherently unworkable nature of the Regulations, which, in the context of the complex products manufactured and assembled by EMA's members, impose obligations relating to the redesign and remanufacture of product components on entities that do not design or manufacture those components.

The net result, as set forth below, is the clear conclusion that the proposed Regulations are fundamentally ill-suited to the types of products manufactured by EMA's members - products that are comprised of thousands of components designed and formulated by a global network of independent component manufacturers, and already subject to comprehensive health and safety regulations. Accordingly, and consistent with the request that the Alliance of Automobile Manufacturers and the Global Automakers submitted on October 8, 2012, the definition of "consumer products" should be revised to exclude the commercial vehicles, engines and equipment manufactured by EMA's members.

### **The Proposed Regulations Will Unlawfully Conflict With Existing Regulatory Programs**

As an initial matter, the Regulations are likely to create unlawful conflicts with other existing regulatory programs. More specifically, with respect to the emissions of air pollutants, including greenhouse gases, engines, vehicles and equipment already are subject to comprehensive and technology-forcing emission standards and other emission-control requirements adopted by the U.S. Environmental Protection Agency ("EPA") under the federal Clean Air Act (42 U.S.C. §§7401, et seq.), and by the California Air Resources Board ("CARB") under the California Clean Air Act (Health & Safety Code §§39000, et seq.). Those standards and other requirements already are at the limit of what is technologically feasible to reduce emissions to near-zero levels, and are elements of an integrated nationwide program that ensures cutting-edge emission controls, while also ensuring that each of the fifty States do not enact separate regulatory programs that could easily frustrate the certification and sale of products that are specifically designed to move in and quite literally drive interstate commerce.

Of particular note and significance in this regard are the express preemption provisions of the federal Clean Air Act. Those provisions prohibit every state and political subdivision thereof, including the DTSC, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from new on-highway vehicles and engines, and from new and non-new nonroad vehicles and engines. (See 42 U.S.C. §§7543.) The only possible exemption from that blanket preemption is provided to the State of California, acting exclusively through CARB. DTSC is afforded no such exemption from federal preemption, however, and so has no authority to adopt any requirements relating to the control of emissions of any air pollutants - - including toxic air contaminants, Proposition 65 substances, greenhouse gases, or other pollutants - - from any mobile sources.

In recognition of the force and scope of federal preemption, the proposed Regulations need to make clear that any engine, vehicle or piece of equipment that is subject to regulation by EPA under the federal Clean Air Act is excluded from the definition of covered “consumer product.” Otherwise, the Regulations will be subject to immediate challenge and invalidation upon their adoption.

The underlying California statutes make this clear as well. Specifically, Health and Safety Code, Section 25257.1 expressly provides that:

- (b) This [green chemistry] article does not authorize the department to supercede the regulatory authority of any other department or agency.
- (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

Simply stated, DTSC is precluded from the outset from adopting any regulation or other requirement relating to the control of emissions from any on-highway or nonroad mobile source. That preclusion is absolute. It is not subject to DTSC’s independent assessment or consideration in the context of designating priority products or regulatory responses. Accordingly, the Regulations must be revised to state unequivocally that the DTSC shall not include in the definition of consumer products any products that are subject to the protections of federal preemption. Otherwise, the Regulations will serve only to foster and engender uncertainty and potential litigation as opposed to consumer safety.

The Regulations are poised to undermine and conflict with other comprehensive health and safety programs as well. For example, in the case of on-highway vehicles, the U.S. Department of Transportation’s (“DOT”) National Highway Traffic Safety Administration (“NHTSA”) prescribes numerous safety standards and requirements. Those Federal Motor Vehicle Safety Standards regulate the design and performance of almost all the major components of motor vehicles, including, but not limited to, brakes, accelerators, lights, tires, steering systems, glass, mirrors, windshield wipers, hoses, controls, seats, seat belts, roof panels, stability control systems, head restraints, impact protection systems, energy absorption systems,

locks, fuel systems, windshields, and interior materials. See, e.g., 49 CFR §§ 571.101, et seq. Additionally, the U.S. DOT's Federal Motor Carrier Safety Administration ("FMCSA") has its own set of comprehensive safety regulations that provide another layer of regulatory control over commercial motor vehicles, primarily affecting their brakes, lights and fuel tanks.

Accordingly, to the extent that the DTSC were to designate almost any vehicle component as a priority product, it would almost certainly create ripple effects that would spill over into the regulatory purview of NHTSA and FMCSA. Similarly, any DTSC-mandated reformulation of vehicle components would almost certainly require parallel regulatory approval processes by NHTSA and FMCSA, which processes could ultimately result in the rejection of proposed alternative component designs. The same holds true with respect to other engine-powered equipment, such as lawnmowers and construction equipment, the design and safety of which is regulated by the Consumer Product Safety Commission ("CPSC"), the Occupational Safety and Health Administration ("OSHA"), and other federal and state agencies.

From the foregoing, it is clear that the DTSC's proposed regulation of the components of highly durable goods - - specifically engines, vehicles and engine-powered equipment - - will almost certainly interfere or conflict with other pre-existing regulatory programs relating to the design, manufacture and assembly of those components. That, in turn, will result in the type of duplicative and conflicting regulations that the underlying California statute expressly prohibits. See Health and Safety Code § 25257.1. The net result is that DTSC should not endeavor to regulate those highly durable goods that are already subject to comprehensive health and safety regulations.

**The Proposed Regulations Should Apply To Component Manufacturers,  
Not Assemblers Of Complex Highly Durable Products**

The conclusion that the DTSC's proposed Regulations should not apply to currently regulated complex products is buttressed by the fact that the Regulations are fundamentally illogical when applied to the components of the highly durable goods manufactured by EMA's members. The Regulations aim to impose mandates for the redesign and remanufacture of components on entities that are not in the business of designing or manufacturing components. That is not only inherently illogical and unreasonable, but unworkable as well.

Engine, vehicle and equipment manufacturers are principally assemblers of the myriad component parts that are designed and manufactured by others. Thus, EMA's members assemble literally thousands of component parts that are manufactured by hundreds of suppliers. Moreover, those hundreds of suppliers are spread out around the world and engage in a world-wide supply and distribution business. They manufacture components that go into engines, vehicles and equipment that are sold and distributed throughout the world. As a result, the structure and dynamics of the engine and equipment industry cannot accommodate unique component design requirements solely for the California market. It is a global supply chain, not one that can be reconfigured exclusively for the State of California. Consequently, in order for components to be effectively and efficiently redesigned and remanufactured in this industry,

those redesigns must be implemented on an industry-wide and world-wide basis. DTSC is not in a position to lead or coordinate that type of global component redesign process for the types of highly complex products at issue.

Just as important, engine, vehicle and equipment manufacturers are not the entities that can implement component redesigns on an industry-wide basis. That is something only the components manufacturers can do. Component manufacturers have the expertise and the actual access to component chemical suppliers that is necessary to implement alternative component designs and formulations in a feasible and potentially cost-effective manner. Manufacturers - - component assemblers at the tail-end of the supply chain - - do not. Thus, the DTSC's regulations are directed at the wrong entities in the supply chain. Stated differently, the focus of the proposed regulatory scheme is upside-down. It seeks to impose mandates that need to be implemented at the beginning of the manufacturing process (the design and fabrication of component parts) by regulating the entity that is situated at the very end of the manufacturing process (the assembler of the components made by others). That creates an inherently impractical and unworkable situation.

Two simple examples can illustrate the illogical and unworkable nature of what the DTSC is proposing for the manufacturers of complex highly durable goods. In the first example, assume that the DTSC seeks to mandate the reformulation of the vinyl that is used in vehicle and equipment seat covers. Vehicle and equipment seats are actually complex systems that are regulated by NHTSA (and in some instances by OSHA or even the CPSC) to ensure crash-worthiness, suitable integration with seat belt systems, lack of flammability, ergonomics, durability and other factors. Moreover, a seat assembly is comprised of hundreds of components made by scores of component suppliers. The complete seat assemblies are typically installed in multiple vehicle and equipment types that are sold and distributed on a world-wide basis.

Accordingly, if seat covering material needed to be redesigned to meet a DTSC mandate, that directive would have to flow all the way up to the global supply chain to the actual seat material maker and its vinyl supplier. Those entities would have to explore alternative formulations and engage in prototype testing. Any new material that emerged from that process would then have to be integrated into the multi-step seat assembly process, so that the new seats could flow back down the global supply chain to vehicle and equipment assemblers. At that point, the integrated seat assembly system would be subject to NHTSA's (and potentially others') review and approval, which could result in additional modifications that would have to flow back up and down the global supply chain all over again. One unavoidable consequence of this tortured process is that in order for the redesign to be commercially viable, it would have to be implemented on a world-wide basis, which would bring even more players and other jurisdictions' regulations (including, specifically, the EU's "REACH" program) into the mix. All of this would create unworkable conflicts, costs and complexities.

This entire process would take many many years, and would involve many many entities outside the control of the vehicle assembler. Indeed, the vehicle assembler might be one of the entities with the least direct control over the entire process.

As a second example, assume that the DTSC seeks to mandate the reformulation of the polymers used in engine piston rings. Piston rings are components of piston systems that are integral to engine performance and durability. Piston rings create the necessary seal between the piston and the piston lining, which provides engine power while also preventing leaks of fuel and lube oils. Piston rings must maintain their structural integrity under extreme heat and very harsh operating conditions, including hundreds of piston strokes per minute over hundreds of thousands of miles of operation.

As in the case of seat covers, the hypothetical DTSC redesign mandate for piston rings would have to flow up the component supply chain to the piston manufacturer and then to its component part suppliers and ultimately to the piston ring maker and its polymer supplier. Those entities would have to try to reformulate and prototype test new piston ring materials that would then have to be integrated into new piston assemblies that would flow back down the global supply chain, ultimately to the engine builder. At that point, since piston rings can have direct impacts on engine emissions, the engine manufacturer would have to engage in extensive engine emissions and durability testing, and would need to obtain proper authorizations from EPA and CARB. Any failed emissions testing could result in the whole process returning to square one. And, due to the time and expense of the redesign process, any new piston ring that emerged would need to be integrated into a wide range of engine applications on a world-wide basis, which again would bring more jurisdictions and more confirmatory testing into play.

The engine manufacturer would not be the principal actor in this process and would not have direct control over the ultimate reformation of the piston ring materials. And, yet, the engine manufacturer would be the "responsible party" under the DTSC's proposed regulatory regime. Once again, that is illogical and upside-down.

These two simple examples reveal the unworkable nature of what DTSC has proposed in the context of complex highly durable goods. Component manufacturers, not component assemblers, should be the regulated entity in the context of complex highly durable goods. As they currently stand, the proposed Regulations fail to account for the inherent lack of control that product assemblers have over the chemical content of product components. The DTSC Regulations also fail to account for the fact that any mandated component reformulations will, in reality, need to be researched and implemented on an industry-wide and, thus, world-wide basis. Individual manufacturers cannot possibly afford the time and cost of requiring redesigned components solely for their own products and solely for California. To the contrary, components for the type of highly complex goods at issues (engines, vehicles and equipment) would need to be redesigned and reformulated on an industry-wide (more likely, world-wide) basis. But the proposed Regulations fail to account for this. This is evidenced, at least in part, by the fact that the DTSC Regulations fail to mention let alone provide for the type of clear-cut antitrust exemption that would be needed to enable the industry-wide collaboration that would have to be undertaken to respond to the DTSC's requirements, just as is provided under the National Cooperative Research and Production Act. See 15 U.S.C. §§ 4301-4306.

In sum, the proposed Regulations are unworkable and directed at the wrong entity in the context of the products manufactured by EMA's members.

**The Proposed Logistics For Implementing  
The Regulations Are Unreasonable And Unworkable**

Turning to the logistics by which DTSC proposes to implement its four-step program, fundamental revisions are required to those aspects of the Regulations as well. Under the proposed Regulations, engines, vehicles and equipment would be included within the DTSC's proposed definition of "highly durable products." That means that the DTSC, subject to the constraints imposed by federal preemption and the underlying California statutes discussed above, could attempt to regulate up to ten (10) separate components of any type of engine, vehicle or piece of engine-powered equipment that the DTSC designated as a "priority product." (See Regulations §69503.4 (a)(2)(B).) As discussed above, that potential outcome under the Regulations as currently drafted is untenable (and illogical) as it would impose wholly unacceptable and unreasonable burdens on the manufacturers of engines, vehicles and equipment. Accordingly, and at the very least, the scope and timeline of the DTSC's proposal need to be revised substantially to make the Regulations workable on even a theoretical basis.

Today's engines, vehicles and engine-powered equipment (hereinafter "engine/vehicle products") are highly complex machines that take multiple years to design, prototype test, and prepare for manufacture and assembly. Engine/vehicle products contain literally thousands of highly sophisticated component parts, including state-of-the-art electronic controls and hardware/software systems that are manufactured by suppliers from around the globe. The coordination and integration of those thousands of parts and suppliers is a logistical challenge that requires years of leadtime to orchestrate, manage and implement. Any disruption of those complex global logistics, such as through a regulatory mandate to redesign and remanufacture up to ten (10) component parts at a time, will cause a cascading chain reaction (as described above) that will upset the delicate balance that goes into the scoping, procurement and assembly of the thousands of components that comprise engine/vehicle products. That, in turn, could result in products essential to California's economy either not being available, or being available at significantly greater cost.

The manner in which the Regulations propose to intrude into global manufacturing processes and logistics fails to account for the complexity, scope and cost of what is at stake. That intrusion is rendered even more unreasonable through the Regulations mandate that only "certified assessors" will be allowed to prepare the requisite alternative analyses. Mandating the involvement of those types of third parties into the global logistics that pertain to the products manufactured by EMA's members would only serve to add additional years of delay and layers of cost to a process that would already be destined to collapse under its own weight.

Turning to the Regulations specific provisions, the DTSC's current proposal to compel the redesign and remanufacture of up to ten (10) component parts at a time is unacceptable and unreasonable on its face. The time and resources required for such an undertaking on the schedule proposed by the DTSC would be overwhelming, and the manufacturers of engine/vehicle products (acting through their "certified assessors") would be called upon to fulfill completely unworkable mandates, involving far-flung component suppliers over which

manufacturers generally have no direct control. The leadtime and logistics that are inherent in the design and assembly of engine/vehicle products simply cannot accommodate the scope of regulatory intrusion that is envisioned under the Regulations as they now read.

At most, the Regulations should authorize the DTSC to specify up to three (3) - - not ten (10) - - components of engine/vehicle products for alternative analyses over any 4-year - - not 3-year - - time period. A minimum four-year period matches the period of regulatory lead time that is guaranteed to manufacturers under Section 202(a)(3)(C) of the federal Clean Air Act. (See 42 U.S.C. §7521(a)(3)(C).) That lead time period is necessary to ensure that manufacturers are not in a perpetual loop of redesigning their products to comply with shifting regulatory mandates. It also provides manufacturers with a sufficient period to try to manage the very significant redesign investments and costs that are necessarily involved in complying with the types of requirements spelled out in the Regulations. Shifting regulatory requirements - - in this instance, for the redesign and reformulation of component parts - - on a more frequent basis will engender unsustainable costs for the engine, vehicle and equipment industries and the related sectors of the economy. Stated differently, without the requisite minimum four-year lead time period, the unreasonable weight and cost of the resulting regulatory burdens on the manufacturers of complex durable goods will cause the collapse of the envisioned consumer products safety program.

Similarly, the timeline for the preparation of preliminary and final alternative analyses must be flexible enough to accommodate the time that manufacturers will need to work the necessary issues up and back down the impacted supply chain to assess and implement potential component redesigns in the context of globalized logistics. In that regard, requiring preliminary alternative analysis reports with 180 days of the listing of components as priority products is unworkable. Equally untenable is requiring final alternative analysis reports within 12-24 months of the DTSC's approval of the preliminary reports. The underlying global logistics for the design, manufacture and assembly of the components that comprise engine/vehicle products requires significantly more time than that. In the absence of a reasonable multi-year timeline, the DTSC's program will simply collapse under its own unsustainable weight.

### **Conclusion**

The proposed Regulations are preempted, inherently unworkable and fundamentally illogical in the context of the highly complex goods manufactured and assembled by EMA's members. Accordingly, in light of all the foregoing issues, and as stated at the outset, the definition of "consumer products" should be revised to exclude the commercial vehicles, engines and equipment that EMA's members produce and distribute on a world-wide basis.

As noted above, EMA's comments are supplemental to the comments that the Coalition has submitted, which comments EMA fully endorses and incorporates by reference. EMA looks forward to working with DTSC staff to resolve the important issues outlined herein and in the Coalition's submission to ensure that the final Regulations are lawful, feasible and cost-effective.

Ms. Debbie Raphael  
October 11, 2012  
Page 9 of 9

If you have any questions, or if you would like to discuss these comments, please do not hesitate to contact me.

Respectfully submitted,



Timothy A. French  
EMA General Counsel

cc: Matthew Rodriquez, Cal/EPA Secretary (via first class mail and email: [matthew.rodriquez@calepa.ca.gov](mailto:matthew.rodriquez@calepa.ca.gov))  
Cliff Rechtschaffen, Senior Advisor to Governor Brown (via first class mail)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor (via first class mail)  
The Honorable Michael Rubio, California State Senate (via first class mail)  
Odette Madriago, Deputy Director (via email: [omadriago@dtsc.ca.gov](mailto:omadriago@dtsc.ca.gov))  
Jeff Wong, Chief Scientist (via email: [jwong@dtsc.ca.gov](mailto:jwong@dtsc.ca.gov))  
Kryisia Von Burg, Regulations Coordinator (via email: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov))



Michael P. Wilson, PhD, MPH  
Director  
LABOR OCCUPATIONAL HEALTH PROGRAM  
2223 Fulton St., 4<sup>th</sup> Floor  
University of California  
Berkeley, CA 94720-5120  
Domestic: (510) 642-5507  
Direct: (510) 642-5703  
International: 011-1-510-642-5703  
(510) 643-5698 FAX

School of Public Health  
Center for Occupational and Environmental Health

October 10, 2012

Debbie Raphael  
Director  
Department of Toxic Substances Control  
California EPA  
1001 I St., 12 Floor  
Sacramento, CA 95812-0806

Dear Director Raphael,

Congratulations on the direction you have provided in moving the Safer Consumer Products Regulations forward and placing California in a position of national leadership in health and environmental protection and in industry innovation in green chemistry.

I am writing to highlight a number of concerns I have regarding the Regulations and the process of their implementation.

- A) **Timing:** Please make every effort to finalize the Regulations and implement them as quickly as possible. I see no compelling rationale for extending the time period for this process.
- B) **Listing Chemicals of Concern:** In examining the evidence, I see no compelling reason to constrain the number of Chemicals of Concern identified in the Regulations. The current number of about 1,200 reflects a minimum number of chemicals identified by credible scientific and governmental bodies around the world. The list catalogues this information, which to date has not been done in any systematic way. This provides a great service to businesses in California that are seeking to reduce their use of recognized toxic substances, and it reflects the practices of leading companies that are currently conducting business in California. It sends a reasonable signal to the market

that some chemicals can and should be recognized as toxic and should be avoided wherever possible.

- C) **Thresholds:** It is important that DTSC retain the authority to set the concentration level in a product for a Chemical of Concern at 0.01% (100 ppm) or lower, rather than allowing for a generalized level of 0.1% (1,000 ppm). It is not appropriate scientifically to set a single standard for all Chemicals of Concern as high as 0.1%, for example, as some substances are more potent toxicologically than others.
  
- D) **Alternative Assessments:** It will be important to streamline the AA process as much as possible. As written, I am concerned that the process could be bogged down, and companies will ask for extensions at each possible opportunity. In evaluating the AA process, my conclusion is that this would best be handled by DTSC in-house, which would avoid the need for accreditation bodies, certified assessors, and monitoring of the activities of these groups by DTSC. It would appear that this option would be less expensive for DTSC if the costs of establishing and monitoring accreditation bodies and assessors are considered. Additional steps are needed to allow public scrutiny of AA documents.
  
- E) **Non-chemical Alternatives:** On page 24, section 69502.2b(4), line 4. It is overly restrictive to allow only for safer chemical alternatives. I recommend that the regulations include the words “or safer engineering administrative approaches that produce a similar, safer function” after the words, “alternative chemical.”

I look forward to working with the Department in moving the regulations forward to the next step. Please let me know if there is any way I or my colleagues can be of assistance to you.

Best regards,



Michael P. Wilson  
Director

# Comments to July 2012 Safer Consumer Products Proposed Regulations, R-2011-02

Peter Sinsheimer Ph.D., MPH, Timothy Malloy, JD  
UCLA Sustainable Technology and Policy Program

10/9/12



These comments do not represent the opinion of the University of California or its Chancellors. Institutional affiliations are for identification purposes only and do not necessarily represent the views of the organization.

| Section    | Sub-section | Topic                                             | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------|-------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Throughout |             | “Contribute to or cause”                          | Throughout the regulations, the terms “contribute to or cause” and “would contribute to or cause” to delineate impacts of concerns or concentrations of concern for chemicals. This imposes too high a standard of causation. The language should be modified to stress that the agency will consider the potential effects. In many cases, simply placing the word “may” in front of “contribute” will be enough. In others, slight rephrasing will be required to capture the concept.                                                                                                                                                                                                                                                                                                                                                                            |
| 69501.1(a) |             | Definitions                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|            |             | Exposure Pathway                                  | Definition of exposure pathway needs to be developed since it is a significant concept for both prioritization of priority products and in the Alternatives Analysis. Section 69503.2(a)(1)(B) can be used as a basis for developing the definition.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|            | 6           | Adverse public health impacts                     | This term should also include public health-related “exposure potential hazard traits” identified in OEHHA’s regulations; namely, “lactational or transplacental transfer” and “particle size or fiber dimension.” It should also include physical chemical hazards. Since the term almost exclusively refers to hazard traits as listed in Chapter 54, the name should be changed to “Public Health Hazards.”                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|            | 59          | Technically and economically feasible alternative | Statute lists these as separate criteria. Since they are fundamentally different they should be evaluated separately. “Feasibility” definitions should relate to whether the alternative is technically <i>possible</i> or economically <i>possible</i> . Definition of technical feasibility in the proposed regulation relates to the possibility of manufacturing the alternative and conforms to standard business definition of the term. Definition of economic feasibility is not related to the possibility of manufacturing the product and does not conform to the basic business definition of the term, and therefore is fundamentally flawed. Business definitions of economic feasibility do not describe the term in relation to whether “the manufacturer’s operating margin is not significantly reduced” as stated in the proposed regulation. An |

| Section         | Sub-section | Topic                                                                      | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------|-------------|----------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 |             |                                                                            | alternative that eliminates the use of CoCs in a targeted product may reduce the operating margin from 100% to 50%, but still generate sufficient return on the investment. Halving the operating margin would be considered “significant” reduction by most people yet most people would consider that a 50% margin economically feasible. The Cambridge Business English Dictionary (Cambridge University Press) defines the term as “the degree to which the economic advantages of something to be made, done, or achieved are greater than the economic costs.” This definition conforms to the definition developed by ECHA in their guidance for authorization of CoCs under REACH. (See ECHA, Guidance on the Preparation of an Application for Authorization, January 2011). ECHA defines the economic feasibility of an alternative as having a positive NPV (net present value) based in existing revenue for the product or possibly increased revenue if the cost for the alternative exceeds existing revenue. Such a definition is not only commensurable with the accepted definition of “economic feasibility” it coincides with the intent of the legislation. |
| 69501.3(a), (c) |             | Signing and certification requirements                                     | This provision significantly enhances the integrity of the program by ensuring that persons in positions of authority at the responsible entity engage in a meaningful way in the process.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 69501.4(d)      |             | Safer Consumer Products Partner Recognition List: Voluntarily completed AA | If an AA is completed by a qualified and certified 3 <sup>rd</sup> party assessor and submitted to DTSC for a consumer product not listed as a priority product but contains one or more CoC and identifies a viable safer alternative, then the agency should be required consider the existence of that safer alternative in identifying Chemicals of Concern under Section 69502.2(b)(4) and prioritizing products under Section 69503.3(d)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 69502.2(b)      | (3)         | Availability of Information                                                | This section gives preference to a chemical that has more data regarding adverse impacts. An absolute presumption such as this could codify the view that absence of data is evidence of (relative) safety. In cases in which there is reason to believe that a chemical may exhibit a hazard trait, the agency should have discretion to view the absence of data as favoring identification. The language “all other factors being equal” does not sufficiently address this issue as it would still make the absence of data a “tie-breaker” in favor of exclusion as a                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

| Section    | Sub-section | Topic                                                                             | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------|-------------|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |             |                                                                                   | CoC.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 69502.2(b) | (4)         | Safer alternatives                                                                | The regulation should identify the effect of identifying a safer alternative; does it weigh in favor of or against identification as a Chemical of Concern? In doing so, the availability of a safer alternative should be used as a factor <b>in favor</b> of identification. The goal of the statute is to advance innovation and adoption of safer alternatives. If a chemical exhibiting a hazard trait is currently in a product and a safer viable alternative exists, this is indication that the market is not itself advancing adoption of the safer viable alternative and that AB 1879 review and regulatory response may be called for. Of course, if the hazard is not significant or exposure is very low, other factors may lead to the conclusion that identification as a CoC is not appropriate.                                                                                                         |
| 69503.3    | (d)         | Process to Evaluate Products Using the Prioritization Factors: Safer Alternatives | If an AA is completed by a qualified and certified 3 <sup>rd</sup> party assessor and submitted to DTSC for a consumer product not listed as a priority product but contains one or more CoC and identifies a viable safer alternative, then the agency should be required consider the existence of that safer alternative in identifying Chemicals of Concern under Section 69502.2(b)(4) and prioritizing products under Section 69503.3(d)                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 69503.3    | (f) (2)     | Priority Product Work Plan – Subsequent work plans                                | A minimum number of new priority products should be required to be listed for each new work plan.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 69503.5    | (c)(3)      | Alternatives Analysis Threshold Exemption                                         | The provision contains no objective standard for setting the threshold. This is even more troubling given the implication in Section 69503.5(c)(1) that the threshold is meant to be driven by the level of unintended contaminants in the product and/or by the minimum detectable concentration. An exclusion from AA should be based primarily on health and environmental factors; i.e. a showing based upon reliable information that the potential for adverse impacts is extremely low—well below what would normally be set as an acceptable exposure level under conventional standard setting methods. Subsection (3) is insufficient to accomplish this goal because it would allow the agency to set a threshold at conventionally derived acceptable exposure limit. It is just this type of standard setting that AB 1879 was designed to avoid through comparative evaluation of products and alternatives. |

| Section | Sub-section | Topic                                                                         | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|---------|-------------|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 69505.2 | (c)         | Responsible entity's own AA process                                           | Responsible entity's own AA process should not be in conflict with guidance provided in 69505.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 69505.3 | (b)(3)(C)   | Step 3, Elimination of Alternatives Posing an Equal or Greater Adverse Impact | <p>Elimination of an alternative on the basis of only public health or environmental impacts is ill-advised. Those two types of impacts by definition do not include consideration of exposure. Thus, one could eliminate an alternative simply based on hazard traits when in fact the exposure profile is such that it is inherently safer than the Priority Product. Also, the comparison should look as aggregate net adverse impacts. This will ensure that the responsible party will assess the overall public health/environmental impacts rather than concentrating on one hazard trait.</p> <p>Any alternative identified by the responsible entity that poses an equal or great adverse impact as the Priority Product should be retained in the Stage One Alternatives Analysis and discussed in the Preliminary AA Report. DTSC should determine the validity of this claim and add all validated alternatives posing equal or greater adverse impacts as Priority Products. DTSC should take such findings into account in crafting regulatory responses for the Priority Product, and in prioritizing products going forward. Otherwise, such alternatives may find a market in California and may also put the regulated manufacturer at a market disadvantage whether or not a safer substitute is identified.</p> |
| 69505.4 | (a)(1)(A)   | Alternatives Analysis: Second Stage                                           | This sub-section discusses retaining only exposure pathway and life cycle factors that have (1) a demonstrable contribution to the adverse impact for either the Priority Product or one or more alternatives AND (2) demonstrable difference between two or more alternatives. Guidance needs to be developed to quantify demonstrable contributions and demonstrable differences. Does data need to be collected on exposure pathways and each lifecycle segment to demonstrate whether or not there is a contribution and whether or not there is a demonstrable difference? Can decision rules be developed to determine the probability of a demonstrable adverse impact and/or demonstrable difference in impacts between alternatives? For example, in implementing an alternatives analysis under REACH, ECHA has provided guidance on whether                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

| Section    | Sub-section     | Topic                            | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|------------|-----------------|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |                 |                                  | exposure needs to be taken into account when evaluated the impact of alternatives to authorized chemicals. (See ECHA, Guidance on the Preparation of an Application for Authorization, January 2011)                                                                                                                                                                                                                                                                                                                                                                                                    |
| 69505.4    | (a)(2)(B) 3.    | Product function and performance | This sub-section calls for the determination of whether there exists a technically and economically feasible alternative. Since this section deals only with technical performance and not economic performance, this sub-section should focus on technical feasibility only. We recommend that technical and economic feasibility be separated into two definitions (see comment above).                                                                                                                                                                                                               |
| 69505.4    | (a)(2)(C) 1.-8. | Economic impacts                 | This list of cost impacts is confusing and overlapping. For example, materials and resource consumption costs are clearly part of manufacturing costs. Business costs are listed along with government agency costs and public costs. How is a business cost defined? Are manufacturing costs part of business costs? Do waste and end-of-life management costs include costs incurred by manufacturer, end user, government? Each term here should be clearly defined.                                                                                                                                 |
| 69505.4    | (b)(6)          | Weighting                        | This section needs to state that DTSC will develop guidance on how to weight relevant criteria                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 69505.5(a) | (2)             | Department Review of AA          | The language should be modified to clarify that the Department has the authority to substantively review the AA Report. For example: "The responsible entity must include in both reports sufficient information for the Department to determine compliance with the substantive and administrative requirements of this article."                                                                                                                                                                                                                                                                      |
| 69505.6(a) | (1)             | Department Review of AA          | The language should be modified to clarify that the Department has the authority to substantively review the AA Report. For example: " Within sixty (60) days of receiving a Preliminary AA Report, the Department shall review the Preliminary AA Report for compliance with the substantive and administrative requirements of this article, including the demonstrations required under Section 69505.4(b). The Department shall issue a notice of its findings with either a notice of compliance or a notice of deficiency."<br><br>Similar changes would be required for Section 69505.6(a)(2)(B) |
| 69505.6(a) | (2)(C)          | Department Review of AA          | Add a new subsection to clarify that the Department may modify the Preliminary AA in the event that the                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

| Section    | Sub-section | Topic                                    | Comment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------|-------------|------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|            |             |                                          | responsible entity fails to comply with the notice of deficiency.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 69505.6(b) | (1)         | Department Review of AA                  | <p>The language should be modified to clarify that the Department has the authority to substantively review the Final AA Report. For example: “ Within sixty (60) days of receiving a Final AA Report, the Department shall review the Final AA Report for compliance with the substantive and administrative requirements of this article, including the demonstrations required under Section 69505.4(b). The Department shall issue a notice of its findings with either a notice of compliance or a notice of deficiency.”</p> <p>Similar changes would be required for Section 69505.6.(b)(3), and Section69505.6(b)(3)(B)</p> |
| 69505.6(b) | (3)(C)      | Department Review of AA                  | Add a new subsection to clarify that the Department may modify the Final AA Report in the event that the responsible entity fails to comply with the notice of deficiency.                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 69506      |             | Regulatory Response Selection Principles | This is a good addition to the regulations, providing clear guidance in the selection of regulatory responses. It should also confirm that the Department is authorized to take a regulatory response on the basis of an approved AA, a disapproved AA or an AA developed by or modified by the Department.                                                                                                                                                                                                                                                                                                                         |
| 69506.11   | (b)(6)      | Exemption from Regulatory Response       | An exemption should not be available if the exemption is inconsistent with the principles established in Section 69506. For example, take the case of a federal or state regulation that addresses an adverse public health impact through engineering controls even though a safer alternative exists. The preference in Section 69506 for inherent protection should prevent issuance of an exemption in that case.                                                                                                                                                                                                               |



**Comments of Unifrax I LLC  
on  
Notice of Proposed Rulemaking  
Safer Consumer Product Alternatives**

**Department Reference Number: R-2011-02  
Office of Administrative Law Notice File Number: Z-2012-0717-04**

**October 11, 2012**

**Introduction**

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF), offers the following comments on the July 2012 proposed regulations for Safer Consumer Product Alternatives, also known as the "green chemistry" regulations.

RCF is a high temperature insulation material that produces energy savings up to 40% or more in industrial furnaces in industries such as petrochemicals, metal forges and semiconductors, as well as other industries such as vehicle emission controls. In these times, it is particularly important to encourage use of such materials where they can be used safely. For over 20 years, RCFC and its members repeatedly have been commended for their dedication to product stewardship and workplace health protection. Since the late 1980's, RCFC and its member companies have developed and implemented a comprehensive Product Stewardship Program (PSP) to control potential workplace and other exposures to RCF. As discussed further below, the RCF PSP has been endorsed by OSHA, NIOSH and EPA at the federal level. The California Occupational Health Standards Board has commended the PSP as well.

The new proposal cuts back on several of the procedural protections provided in prior drafts:

- (1) The exemption for "bulk chemical products" not sold directly to retail consumers has been eliminated;
- (2) The exemption for exposure pathways regulated under other state or federal regulations has been eliminated, and this issue has been reduced to one of many general considerations in the priority product determination,
- (3) The definition of "feasibility" with respect to potential alternative products has been revised and narrowed to exclude certain external economic factors.

The final regulations should restore these protections as provided in the prior drafts. In addition, the final regulations and statement of reasons should clarify the following:

- (1) Existing regulation of a potential exposure pathway should be deemed adequate where additional regulation has been investigated and found to be unwarranted; and
- (3) Existing regulation should include product stewardship programs that have been determined by regulatory authorities to provide adequate protection.

These points are discussed below, following a summary of current RCF uses and potential exposure in California.

### **RCF Uses and Potential California Exposures**

RCF is a synthetic vitreous fiber first discovered in 1942 and commercialized in the 1960s. RCF is the smallest segment of the synthetic vitreous fiber industry, representing about 2% of total production, and is used primarily in industrial applications. Approximately 100 million pounds is produced annually in North America,

with between 5-6% sold into California (representing approximately \$9.4 million in sales). The total exposed population in the United States is approximately 26,000 workers, approximately 1,300 of which work in California end user plants.

RCF is an energy efficient insulation capable of very high temperature applications, up to 2800°F. RCF is an important product for furnaces, heaters, and reactors in the petroleum, petrochemical, chemical, fertilizer, steel, heat-treating, nonferrous metals, glass, ceramic, foundry, cement, and forging industries. Other uses are in fire protection, automotive catalytic converters, heat shields, air bags, aerospace, and defense applications. It is produced in a variety of forms, including bulk, blanket, modules, paper, felt, and textiles.

Globally, RCFs play an important energy efficient and environmentally friendly role by controlling high temperatures and reducing fossil fuel consumption. U.S. production of RCF is sold primarily into industrial furnace markets, saving an estimated 164 trillion BTUs annually, equivalent to 27.8 million barrels of oil, near \$1.4 billion at \$50/barrel, a huge impact on the US economy. As a superior energy efficient insulation product, RCF plays an important role for industry both in California's aggressive initiative under AB 32, as well as regional, national and international efforts, to reduce greenhouse gas emissions. For example, in a *single* 2,000 square foot batch (cycling) furnace, such as would be used in the metals processing or ceramic industries, RCF insulation would save \$200,000 to \$500,000 annually as compared to more traditional insulations, depending upon the fuel used for the furnace. In an environmental context the reduction in CO<sub>2</sub> emissions would range from approximately 1,100 to 1,600 metric

tons annually; this savings would be equivalent to removing from 230 to 315 cars from the highway.

RCFs are produced using a melt fiberization process, under highly controlled conditions, similar to processes for manufacturing other synthetic vitreous fibers (e.g., fiberglass and mineral wool). Primary fibers are produced in five plants in the United States and two in Mexico. Thus, the principal impact of the proposed PEL is on industries located in California that use RCF in critical applications. Those industries include:

➤ Petrochemical industry:

- Most furnaces have been designed to use RCF products because it is far lighter than other refractory products (for example, RCF weighs 8-10 pounds a cubic foot, while denser refractories can weigh between 65-150 pounds per cubic foot).
- If unable to use RCF in petrochemical furnaces, the impact would be very significant, particularly in terms of energy use since other refractories (with poorer insulation properties) require many more Btu's per hour because of the energy required to heat the furnace walls. Retrofit of a furnace to accommodate conventional refractories would virtually require a new furnace designed to accommodate heavy refractories.

➤ Forging industry

- Most furnaces are lined with RCF and use natural gas to heat to high temperatures.
- RCF is much lighter and has superior insulating properties. Furnaces can be cycled, and even idled; heating up for use takes as little as an hour and a half, while thermal shock is a real issue for other refractories thereby making cycling more difficult.
- If forced to use firebrick or other denser refractories, the cost of natural gas and refractories themselves in a cycling furnace would skyrocket.

➤ Semiconductor industry

- RCF is used in diffusion furnaces, where it supports the quartz tubes used to run gases such as argon through the furnace, to provide the appropriate thermal conductivity.

- RCF is also used in vestibule block at the end of the furnace; the vestibule blocks are made from vacuum formed RCF and are also circumferentially encapsulated in RCF blanket.
  - While the amount of RCF used in the semiconductor industry is relatively small compared to the amount used in the petrochemical and forging furnaces, the impact on the marketplace in California would be substantial. Without the ability to use RCF in diffusion furnaces, numerous companies in Silicon Valley would be required to re-engineer this process at substantial cost.
- Emission control industry
- RCF emission control products for diesel and other mobile source emissions play a vital role in providing the control devices essential for compliance with state and federal emission control regulations.

### **Bulk Chemical Products**

The prior draft regulations included a provision exempting the following products from preparation of alternatives assessments:

A bulk chemical that is placed into the stream of commerce in California and that meets the definition of a “consumer product”, as defined in Health and Safety Code section 28 25251, but that is not packaged for sale to, or end use by, a retail consumer.

Unifrax supported this provisions as consistent with the applicable legal requirements and the intent of the enabling legislation. However, it has been eliminated from the present proposal.

Unifrax urges DTSC to include this exemption in the final regulations. The program is intended to protect against adverse effects from consumer exposure to chemical products, including potential effects on sensitive subpopulations such as infants and children (Section 25252(a)). Bulk products, such as RCF shipped to CA for further processing, present no potential for such exposure provided other applicable regulations are satisfied. Further, as discussed below this program is not to duplicate or supersede other regulatory requirements. In case where exposure to bulk products is

limited to workplace settings, and the applicable workplace requirements are met, no further regulation under this program is permitted.

It appears that the exemption in the prior draft would only apply to the requirement that manufacturers of priority products must prepare an alternatives assessment. Accordingly, while it would not prevent a product from being listed as a priority product, if listing were to occur no alternatives assessment would be required. Unifrax supports this approach but urges DTSC to consider it at an earlier stage in the process where warranted. For example, if it is clear that a particular product is likely to be exempt from the alternatives analysis under this provision, it should not be listed as a priority product.

### **Existing Regulation**

Under the prior proposed regulations, a product could be exempted from the listing and subsequent regulatory processes if the Department determines that existing regulation is adequate throughout the life cycle of the product and there are no significant gaps in regulatory coverage. This exemption also has been deleted from the current proposal and replaced with a provision that makes existing regulation only one of many considerations in the priority process.

The proposed approach is not consistent with the governing statute. Section 25257.1 provides: "(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency. (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." This language is clear: existing regulation cannot be superseded or duplicated. Thus, an

exemption is required for potential exposure pathways already regulated. Demoting this consideration to one of many in the priority process, which the Department presumably could overrule in some cases, is a violation of the statute. The prior exemption should be reinstated in the final rule.

The Department also should clarify that existing regulation of a potential exposure pathway is deemed adequate where additional regulation has been investigated by regulatory authorities and found to be unwarranted. With respect to RCF, such conclusions have been drawn by the federal authorities at EPA, OSHA and NIOSH, respectively.

#### EPA

The current regulatory focus on occupational RCF exposure is a direct result of an EPA investigation of RCF pursuant to the federal Toxic Substances Control Act (TSCA). In 1991, EPA initiated an accelerated review of RCF under TSCA Section 4(f). The Section 4(f) review could have resulted in a ban or other regulation of RCF pursuant to TSCA Sections 5 or 6, or referral of the issue to OSHA for regulation pursuant to TSCA Section 9. It could also have resulted in regulation of RCF as an "imminent hazard" pursuant to TSCA section 7.

Section 4(f) requires a 6-month expedited review. At the conclusion of the RCF review period, EPA determined that the available RCF studies were not a sufficient basis for determining whether RCF exposures pose significant or unreasonable risk. In view of this decision, EPA decided to continue its investigation of RCF data through negotiation of a consent agreement order under TSCA Section 4 to obtain additional exposure monitoring. The agency also decided to consider a "significant new use rule"

(SNUR) regulating new uses of RCF. No other regulatory action was proposed. The subsequent Federal Register notice of March 21, 1994, proposing the RCF SNUR, describes the results of the 4(f) review:

On November 21, 1991, the Agency concluded that, based on animal inhalation data submitted to the Agency under section 8(e) of TSCA, RCFs may present an unreasonable risk of cancer to human health. After conducting an accelerated review of RCF under section 4(f), EPA concluded there was not sufficient data available (particularly on exposure to and substitutes for RCF) to determine whether or not RCFs present an unreasonable risk. However, there was sufficient basis for human health concerns to initiate a regulatory investigation of RCFs to determine whether action under TSCA section 6 to control the use of RCFs was appropriate. The regulatory investigation of RCFs includes a thorough review of a recently completed multiple dose animal inhalation study, an update of the findings from an ongoing worker epidemiology study, an analysis of substitutes, and development of comprehensive exposure data. (EPA and three of the six domestic manufacturers of RCF have recently entered a consent agreement which provides for the collection of exposure monitoring data from the facilities of the participating companies and their customers.)

EPA has never adopted a final SNUR for RCF. Following the 4(f) review, the RCF industry signed a monitoring consent agreement with EPA that led to development of the current PSP and REG. The monitoring data and the studies of other potential exposure pathways, discussed further below, have led both the industry and regulators to focus on occupational exposures as the only potentially significant RCF exposure pathway. This in turn led to the current agreement with OSHA and NIOSH Criteria Document for RCF, also discussed further below. Over the years, the industry routinely has included EPA staff in PSP updates and has interacted extensively with EPA scientific staff reviewing and developing RCF health data and analyses pursuant to the agency's Integrated Risk Information System (IRIS). To date, these activities appear to

have convinced EPA staff that the conclusions of the 1991 review remain valid and that no further action is necessary.

In the early 1990s, EPA also proposed to list RCF as a hazardous substance for purposes of hazardous waste and Superfund regulation, as well as reporting under the Community Right to Know rules. The bases for the proposal were the listing of "fine mineral fibers" as a hazardous air pollutant in the Clean Air Act Amendments of 1990, and an early IRIS listing for RCF that described the scientific data available at the time. The proposed RCF listing was not finalized. The Clean Air Act listing does not apply because it is limited in the statute to "mineral fiber emissions from facilities manufacturing or processing glass, rock, or slag fibers (or other mineral derived fibers) of average diameter 1micrometer or less." The IRIS listing was not used because EPA had concluded in the 1991 TSCA 4(f) review that the same studies were not a sufficient basis for RCF risk assessment.

### OSHA

One of the basic findings of the RCF 4(f) review and subsequent exposure monitoring is that potential risk is confined to workplace exposures. In more recent years, this has led the industry to focus its efforts on interactions with OSHA staff. The two PSP programs that OSHA has endorsed, PSP 2002 and PSP-HTW, are the culmination of these efforts.

The OSHA letters endorsing the two PSP programs do not contain any findings that they are necessary to prevent significant workplace risks, but do acknowledge that they are effective methods for risk reduction. For example, the February 11, 2002 from OSHA head John Henshaw (at that time) states:

Although the success of PSP 2002 cannot be evaluated until the progress reports specified in the Program are reviewed, the actions that RCFC has committed to take help address the concerns that led to OSHA's identifying synthetic vitreous fibers (SVF), including RCF as a high priority for action... OSHA does not, at this time, consider RCF a regulatory priority.

The same letter goes on to state:

OSHA believes that the commitments RCFC has made in developing this Program form an important step towards further improving worker protection. The 0.5 fiber/cc exposure guideline recommended in the Program, the specific engineering controls and work practices detailed in the Program, and the recognition that respiratory protection is appropriate in certain operations will help reduce exposures of the workers who handle RCF products daily. . . .

By letter of May 23, 2007 from OSHA head Edwin Foulke, OSHA reaffirmed its commitment to the most recent update of the RCF PSP, PSP-HTW. The letter does not contain any finding that the PSP or the REG are necessary to prevent significant workplace risk, nor does it suggest that any more recent data are sufficient to cause reconsideration of this issue.

### NIOSH

NIOSH issued a Criteria Document for RCF (#2006-123) in 2006, after an extensive review of available literature and data both by NIOSH scientists and external experts. NIOSH initially considered adoption of an REL of 0.2 f/cc but ultimately elected to adopt 0.5 f/cc REL, consistent with OSHA and the industry's REG.

### Cal OSHA

In California, RCF is subject to two different occupational exposure limits. On the federal level and in all other states, the applicable standard is 0.5 fibers per cubic centimeter (f/cc). As discussed further below, 0.5 f/cc is the Recommend Exposure

Guideline (REG) in the industry's PSP, which has been endorsed by federal OSHA and NIOSH and can be enforced by OSHA.

In 2009, the California Occupational Safety and Health Standards Board adopted a state permissible exposure limit (PEL) for RCF of 0.2 f/cc. In adopting this PEL, the Board stated:

The Standards Board would like to note that it applauds the RCF industry's support of research on the potential hazards of RCF, and the product stewardship effort of RCF producers. The RCF industry has collected exposure data under a quality assurance project plan designed in conjunction with Federal EPA. These data have been shared with the Division as well as U.S. Department of Labor and other interested regulators. These data show that, with the help of RCF producers, users have achieved average TWA exposures well below the voluntary limit of 0.5 f/cc and in most circumstances at or below the proposed PEL of 0.2 f/cc. Therefore, in light of the totality of evidence cited by ACGIH and NIOSH on the potential for RCF to cause or contribute to respiratory disease, the Standards Board believes that a PEL for refractory ceramic fiber of 0.2 f/cc is feasible and necessary to protect workers.

The Standards Board appreciates the concerns raised by RCFC that, although measurements of airborne exposure to RCF for some operations have averaged below 0.2 fibers/cc, the variability of the results indicates that employers cannot assume that a single sample on any particular day will always indicate an 8-hour TWA exposure that does not exceed this level. These employers will have the option of supplementing engineering controls with respirator use or finding ways to improve engineering controls.<sup>1</sup>

Unifrax disagreed with the Board's decision and continues to believe that the 0.5 f/cc REG is the most appropriate standard for RCF exposure, as the federal authorities have recognized. Unifrax is committed to compliance with the Cal OSHA standard as the workplace standard in CA, and understands that the Cal OSHA standard will be the governing workplace standard under these regulations. However, in evaluating other

---

<sup>1</sup> Occupational Safety and Health Standards Board, "Final Statement of Reasons, Airborne Contaminants," p. 30 (Public Hearing March 19, 2009). A detailed discussion of RCF issues can be found on pp. 28-52 of this document.

potential exposure pathways Unifrax believes that the 0.5 f/cc REG is the most appropriate standard. We believe this is fully consistent with the statutory directives to consider "worker safety and public health" and to "use, to the maximum extent feasible," information and standards developed by other public or private regulatory bodies.<sup>2</sup>

### **RCF Product Stewardship**

For purposes of these regulations, existing regulation should include product stewardship programs that have been determined by regulatory authorities to provide adequate protection. Again this is fully consistent with the statutory direction to place maximum reliance on the work of other public and private regulatory bodies.

The principal U.S. manufacturers of RCF began in-plant and customer monitoring of RCF exposures in the 1970s. A formal *product stewardship program* (PSP) was adopted in 1990, was incorporated in a consent order with EPA in 1993 and endorsed by OSHA as discussed above, first as PSP-2002 and then again in 2007 as PSP-HTW. The following is a summary of the elements of PSP-HTW.

Scope. The PSP applies to the manufacture, fabrication, furnace-lining installation and removal, and other settings where exposure to RCF may occur. RCF manufacturers are directly responsible for compliance at their own operations, and undertake the various activities described in the PSP to encourage customer compliance. The PSP grew in part from a voluntary Consent Agreement negotiated with EPA in the 1990s, which was the first such agreement ever to provide for monitoring at user operations. Subsequently, several user groups have formed trade associations to encourage PSP compliance. The Refractory Ceramic Fiber Coalition

---

<sup>2</sup> Health and Safety Code Sections 25252(b)(2), 25252.5(b)(4).

(RCFC) maintains a website, [www.rcfc.net](http://www.rcfc.net), to provide updates information for its customers and the public.

Recommended exposure guideline. As discussed above, the PSP includes a recommended exposure guideline ("REG") of 0.5 f/cc, 8-hour time weighted average (TWA). The REG is based upon the data obtained pursuant to the PSP and EPA Consent Agreement, which indicates that it is generally feasible to maintain a workplace concentration of 0.5 f/cc with engineering controls in many RCF operations, and the RCFC philosophy that it is prudent to implement feasible and necessary workplace engineering controls.

The PSP is generally premised upon an intent to reduce RCF exposures to the lowest feasible level. The REG is a useful benchmark in this regard. Where it is feasible to reduce workplace concentrations to levels below 0.5 f/cc, the industry recognizes that it is prudent to do so and recommends continued efforts to maintain the lowest levels consistently achieved. As discussed above, to ensure that workplace concentrations below the REG of 0.5 f/cc are attained consistently, it is frequently necessary to maintain concentrations below that level. These aspects of the PSP were cited by OSHA as particularly important in its decision to support the PSP.

Control measures. The PSP obligates manufacturers to use product design, engineering controls, work practices, respiratory protection or a combination thereof to achieve, for each of its workers, exposure control consistent with the PSP provisions. While engineering controls are used where feasible and necessary, the industry may utilize other techniques to assure worker protection. In such cases, RCFC and its members strive to ensure that any changes to product properties do not lead to an

increased compliance burden on the part of users. Where workplace exposures are currently below the voluntary 0.5 f/cc, 8-hour TWA REG, RCFC and its member companies are committed to a continuing improvement program to reduce workplace exposure further. RCFC and its member companies also provide information to RCF product users regarding exposure control techniques and best practices. On a case-by-case basis, assistance or guidance is provided to end-users and they are encouraged to develop and implement effective exposure controls.

Work practices. The RCF manufacturers encourage employers and employees to follow proper handling guidelines for RCF. RCFC provides recommended work practice guidelines, in both video and written format. These work practices include recommendations for cost-effective engineering controls, proper respirator use, use of protective clothing and workplace handling guidelines.

Worker training. The RCF manufacturers provide health and safety training for their employees consistent with applicable OSHA requirements for Hazard Communication. We also provide health and safety training to end-users, consistent with targets established in the PSP. We participate in trade shows, conferences and other relevant events that provide suitable forums for communicating RCF-related health and safety information and guidance to end-users. We have developed a communications program designed to promote and advertise training seminars and other training opportunities.

Respirator use. RCFC and its member companies support OSHA's respiratory protection standards, which form the basis for RCFC's respiratory protection program. RCFC's training programs and materials incorporate all relevant requirements of

OSHA's respiratory protection standard. Appropriate respiratory protection is used when employee exposures are not "reliably" below industry guidelines (based upon task-specific information; preferably employer-specific data, but relevant data from other sources may also be used). We recommend the use of appropriate respiratory protection to end-users, in the circumstances where occupational exposures may exceed industry guidelines and effective engineering controls are not readily available. When workers use respirators, RCFC recommends the use of respirators certified by NIOSH under 42 CFR Part 84. RCFC, in consultation with the EPA, OSHA, NIOSH and other parties, reviews the program periodically and modifies it expeditiously where a change is appropriate.

Medical monitoring. RCF manufacturing companies maintain medical monitoring programs for workers producing RCF, consistent with acceptable surveillance practices and protocols. The medical monitoring program was designed by epidemiology researchers at the University of Cincinnati to investigate and identify any incidence of RCF-related health effects. In particular, the study employs chest X-rays and spirometry tests to identify potential instances of fibrosis, lung cancer or mesothelioma.

Product research. The PSP encourages research to develop new, improved RCF product forms. New RCF product research generally focuses on three key elements - dose, dimension and durability. To reduce the potential for worker exposure (i.e., reduce dose), various methods are being explored to contain RCF. RCFC members investigate options to alter the size distribution (i.e., dimension) of RCF to reduce the fraction in the respirable range (less than 3 microns in diameter) while maintaining key performance properties. In the past decade, great progress has been made, pursuant

to this program, in developing and marketing more soluble fiber products suitable for many RCF applications.

Waste minimization and disposal. Pursuant to the PSP, RCF manufacturers continue to study, recommend and implement waste minimization programs designed to reduce quantities of waste produced per unit of product and to increase recycling rates where practicable and effective. RCFC also continues to study and recommend after-service and solid waste handling procedures of RCFC members and their customers and to recommend appropriate handling procedures for disposal of friable RCF wastes.

Environmental responsibility. The PSP obligates RCFC members to design and/or modify their processes so as to minimize consumption of natural resources and energy and to eliminate, to the extent feasible, the generation of waste materials and releases to the environment. In so doing, the companies continue to focus on source reduction as the preferred approach to waste management, followed by internal recycle/recovery. Treatment or disposal is employed as a last resort. We strive to design and/or modify products and packaging in a manner that minimizes environmental impact throughout the product's life cycle. This includes ultimate disposal in a manner that assures that all applicable regulatory requirements are met.

Reporting. The RCF manufacturers generate annual reports to document PSP progress. We submit copies of the annual PSP reports to OSHA, NIOSH, EPA, and various user associations. These reports provide exposure monitoring results and information on program performance, including progress on program deliverables and specific measures of program performance. The reports also provide the latest available information from the RCFC epidemiological study and medical surveillance

program. In addition, RCFC keeps OSHA, NIOSH and EPA officials informed of significant developments in the scientific and medical assessment of RCF products through periodic informal meetings.

Exposure monitoring. Another key component of the PSP for RCF is exposure monitoring. Results of this program have been published extensively in the peer-reviewed literature. The most recent publication from the journal *Inhalation Toxicology* was authored jointly with personnel from OSHA and NIOSH.

RCF manufacturers monitor fiber concentrations in their respective plants. And, time trends show that exposures have been reduced in these facilities. But the program has a much broader scope; personnel from RCFC member companies also monitor their customers. As a result the industry has a substantial body (now 18 years and well over 17,000 samples) of monitoring data, indicating consistently that the industry has made substantial progress in reducing weighted average exposures at customer facilities.

Health studies. Various animal studies commissioned by the RCF manufacturers in the 1980s appeared to confirm that RCF was an animal carcinogen under certain test conditions, e.g., the "maximum tolerated dose" (MTD) of approximately 200 f/cc inhaled directly into the lungs. A later review of the MTD pathology indicated that the animals' lungs were "overloaded" because of large quantities of non-fibrous particles, and that this overload condition was likely responsible for the disease observed. In fact, evaluation of the aerosol samples used confirmed the presence of significant quantities of particulate matter. In a subsequent multi-dose animal inhalation study at 25 f/cc, 75

f/cc, and 115 f/cc; a *no observed effect level* (NOEL) was found at 25 f/cc. This level is 50 times the RCFC recommended REG of 0.5 f/cc for humans.

The RCF manufacturers also have engaged the University of Cincinnati (UC) to conduct a long-term medical surveillance study on RCF workers. This continuing study has been in progress for over 20-years, collecting data from respiratory questionnaires, lung function tests, chest X-rays, exposure monitoring, and worker mortality. The results of this study of RCF plant workers exposed from 1953 to the present have shown:

- No excess mortality related to all deaths, all cancers, or lung cancer
- No statistically significant increase in interstitial findings (fibrosis), and
- No mesotheliomas

Thus, this long term epidemiology study has demonstrated both an absence of interstitial fibrosis, no increased mortality risk and no decrement in lung function associated with current exposures.

Since there has never been human disease associated with exposure to RCF, a risk assessment based on cancer endpoints in humans is impossible. Thus, RCFC commissioned a risk assessment based on the bioassay data from the animal studies described above which were conducted at RCC Laboratories in Geneva, Switzerland during the late 1980's. *Sciences International Inc.*, a world renowned environmental consulting firm, conducted the risk assessment in 1998 based on the RCF animal studies. The risk assessment team was led by Dr. Suresh Moolgavkar and utilized the two stage clonal expansion model.

The model looked at fiber lung burden in the animals along with deposition and clearance in both humans and animals, allowing for estimates of risk based on lung burden only. The calculated risk for a 70 year old worker with 30 years of exposure to 1

f/cc was  $3.7 \times 10^{-5}$  (maximum likelihood estimate) for a nonsmoker and  $1.5 \times 10^{-4}$  for a smoker. Further work by Moolgavkar and coworkers has shown the importance of fiber biopersistence on carcinogenic potential. Fiber chemistry influences carcinogenicity primarily through its role in biosolubility. Using the Moolgavkar work, Turim and Brown 2003 summarized the 95% upper bound risk of excess lifetime lung cancer for nonsmoking workers as:

- $3 \times 10^{-5}$  for a 1 f/cc exposure
- $1.5 \times 10^{-5}$  for a 0.5 f/cc exposure
- $0.3 \times 10^{-5}$  for a 0.1 f/cc exposure
- Separately, Fayerweather (1997) extrapolated rat data to human data using a linearized multistage model and found at exposures of 1 f/cc, the excess lifetime risk of developing lung tumors was  $3.8 \times 10^{-5}$  (maximum likelihood estimate).

Subsequently others have modeled animal data yielding similar risk estimates.

Pursuant to the PSP RCF manufacturers have undertaken a comprehensive analysis of all potential RCF exposure pathways. As discussed above, these efforts have been endorsed, and relied upon in lieu of regulation, by federal authorities at OSHA, NIOSH and EPA. The essential conclusion has been that occupational exposure is the only potentially significant human exposure pathway for RCF, and that the PSP has been effective in preventing harmful occupational exposure. The final regulations and Statement of Reasons should clarify that under these circumstances, existing regulation should be deemed to include industry product stewardship programs such as the RCF PSP.

### **Alternatives Analysis**

The prior regulations defined "feasibility," for purposes of potential alternative products, as follows:

As part of a determination of whether a “technologically and economically feasible alternative” exists, the responsible entity shall consider all of the following, to the extent applicable: (a) The extent to which a functionally acceptable alternative is currently available in the marketplace; (b) the affordability of any currently available functionally acceptable alternative; and (c) the purchase price differential between the Priority Product and the alternative.

The current proposal changes this:

"Technically and economically feasible alternative" means an alternative product or chemical for which: (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and

(B) The manufacturer’s operating margin is not significantly reduced.

Unifrax urges the Department to retain the prior definition in the final regulations.

Feasibility determinations should be based on acceptable alternatives that are currently available, and the affordability of any such alternatives. It should not be based on speculation as to products that are "expected to be sufficient." The new definition will lead to required alternatives that have not been demonstrated to be feasible, and in fact are not feasible, in various relevant markets.

Unifrax also notes, as indicated above in the summary of RCF uses and potential exposures, that several of the other factors specified in the statute for evaluation of alternatives are particularly applicable to RCF. These include:

- Product function or performance
- Materials and resource consumption
- Air emissions
- Production, in-use, and transportation energy inputs
- Energy efficiency
- Greenhouse gas emissions

Unifrax urges the Department to adopt final regulations that include the prior definition of feasibility and state clearly that all of these factors are to be considered in the analysis of potential alternatives.

#### Conclusion

For the reasons stated above, the final consumer product regulations and accompanying Statement of Reasons should:

1. Reinstate the prior exemption for bulk chemical products;
2. Reinstate the prior exemption for existing regulation;
3. Clarify that existing regulation of a potential exposure pathway is adequate where additional regulation has been investigated and found to be unwarranted;
4. Clarify that existing regulation includes product stewardship programs that have been determined by regulatory authorities to provide adequate protection; and
5. Reinstate the prior definition of feasibility.

Respectfully submitted,



UNIFRAX I LLC

Dean E, Venturin, Ph.D  
Director, Health Safety and Environment

October 11, 2012

Krycia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control (DTSC)  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Unilever's Comments to the Proposed "Safer Consumer Products" Regulation

Dear Ms. Von Burg:

We are contacting you with Unilever's comments on the proposed "Safer Consumer Products" regulation.

Over the past four years, Unilever, a global consumer products company with manufacturing facilities in California in City of Industry, Sunnyvale, and Stockton, has been participating in the California Green Chemistry Initiative through our industry trade associations, including the: Grocery Manufacturers Association (GMA); Personal Care Products Council (PCPC); American Cleaning Institute (ACI); the industry coalition known as the Green Chemistry Alliance (GCA); and, more recently, with the Consumer Specialty Products Association (CSPA).

We support the comments which these organizations are sending in separately, but there are several additional comments which we would like to make.

#### Introduction

Unilever manufactures a wide range of personal care products for the California market. We assess the safety of these products to ensure that they will be safely used by our consumers. We also ensure that we comply with both federal and state regulations.

For years, Unilever and our trade association representatives have lobbied in support of bipartisan measures to create a science-based framework for chemicals management. This was true in 2008 with the passage of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). The driving force behind industry's efforts has been a broad based desire for state regulators, rather than legislators, to exercise their expert scientific and engineering judgment and experience when promulgating appropriate regulatory provisions affecting chemicals of concern in consumer products.

The Green Chemistry Alliance (GCA) has advocated the crafting of regulations to enable the DTSC to fully and successfully implement AB 1879 and SB 509, which would provide for comprehensive chemical management and in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development. In a proactive fashion

and in response to DTSC's requests for comments, GCA stakeholders have invested countless hours over the last several years developing regulatory text and comments for implementing the regulation. This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy.

We recognize the extensive DTSC staff efforts that have gone into the proposed regulatory revisions from 2011 and into 2012, plus the support of Director Raphael's efforts to make the Safer Consumer Products regulation "practical, meaningful, and legally defensible." Unilever is hopeful that, upon adoption, the final regulation will:

- 1) be forward-looking in order to identify, prioritize, evaluate and regulate the highest priority chemicals of concern in high priority consumer products;
- 2) promote truly safer alternatives on the basis of comparative multi-media life cycle evaluations;
- 3) consist of a comprehensive set of regulatory concepts that are within (a) the authority of and (b) fully satisfy the substance of the enabling legislation;
- 4) allow for a clear, timely and effective implementation in an orderly and economically responsible manner; and
- 5) provide clarity regarding compliance and enforcement.

#### Positive Features of the Proposed "Safer Consumer Product" Regulation

The proposed regulation contains a number of items which will help to create a program that could deliver the desired result.

- The regulations describe an approach which DTSC indicated will identify approximately 185 Chemicals of Concern (COCs) for the first 3 years of the program. Unilever supports the narrowing of the list of COCs, as long as information on the chemical hazard plus indicators of exposure to the citizens of California are used to prioritize and narrow the list of candidate COCs to a workable number.
- Unilever also supports the idea that, in the first round, DTSC will only pick up to 5 Priority Product/COC pairs to enable DTSC to learn, from actual case studies, what the issues are in implementing the regulation.
- The Alternative Analysis (AA) section of the current proposed regulation has some important improvements over earlier versions of the regulation. Unilever has spent considerable time and effort, notably in the workshop of September 15, 2011, to give examples of how our industry currently manages its everyday programs of assessing alternatives, for a wide variety of reasons. We support the fact that the proposed regulation expects companies to conduct alternatives assessments, using the skills in this area built up over many years, to reach their own conclusions on potential product changes, without having the answer pre-determined by DTSC, which, in all

due respect, does not have the years of experience in the formulation of consumer products that the companies have.

- Two additional positive changes are provided with the current proposed regulation: (a) elimination of the need for 3<sup>rd</sup> party verification; and (b) the added ability of being able to use in-house expertise to develop AA's. These changes will allow an alternative assessment to be completed more efficiently, since significant expertise resides in the companies, thereby allowing DTSC to reach its implementation goals more quickly.

## Issues with the Proposed "Safer Consumer Products" Regulation

There are still numerous concerns, however, which Unilever has regarding the proposed regulation. In our view, these must be addressed in order for the regulation to achieve its goal of providing improvements in the safety of consumer products. One overarching concern is that the inter-related requirements of the regulation will actually stifle true product and chemical alternatives innovation, simply because of the amount of unnecessary work that would be required even just to make a simple substitution of an ingredient. All this work requires resources, which will be otherwise diverted from focused innovation projects that serve as the lifeblood of all consumer product companies.

The goal of the underlying statute of AB 1879 is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. However, the proposed regulatory approach could create an unpredictable framework which will only increase uncertainty for companies doing business in the state of California.

While Unilever supports the commitment by DTSC to life cycle thinking in evaluating alternatives to current chemicals of concern, there are other factors that are important to companies doing AA's which the proposed DTSC regulations have completely failed to address. For example:

### 69501.1(a)(56) Definition of Safer Alternative

The proposed regulatory definition used by DTSC is that a "safer alternative" "means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts".

This definition needs to be significantly changed. While using a "safer" alternative to a chemical of concern may theoretically result in a "safer formulation" for a given product, to the extent that there may have been a negative public health or environmental impact associated with the original product, the use of a "safer alternative" may not actually reduce any such risk.

In addition to evaluating the human and environmental safety of a product, including a proposed alternative product, consumer product companies also must ensure that the product be evaluated for microbiological and physical safety. It is possible to take the safest, “greenest” ingredients (i.e., “safer alternatives”) and make a toxic product if the product is manufactured in a hygienically unsafe manner or if the product is not preserved properly to prevent microbiological contamination and growth of microorganisms. As such, in order to prevent microbiological contamination, there may be times when certain minor amounts of chemicals may be required to ensure total product safety – even if the chemical is not deemed the safest alternative under the proposed regulatory program. So, the regulation needs to recognize the distinction between the potential risk associated with an ingredient versus the potential risk of the final product. Physical safety also includes the choice of packaging material, as some forms of packaging provide the consumer with the ability to use a product more safely (for example, using plastic packaging instead of glass for certain applications). If either of these issues are not addressed adequately, the final product could present significantly more acute safety issues to consumers than many of the supposed chemicals of concern in a product that are the subject of the “safer alternatives” concept.

## Legal Factors

Patent considerations and market availability must also be part of any alternatives analysis, as companies may be prevented from using DTSC’s preferred chemical or process simply because another company holds a patent for that preferred chemical and it is not willing to grant a license to another entity to use the patented preferred chemical. So, there needs to be regulatory recognition of whether the “safer alternative” is truly readily available in the marketplace. Clearly, DTSC would not mandate that a company violate a patent just because it considers its use to be a “safer alternative.”

## 69505.1.(e) Certified Assessors

Unilever has significant reservations about the role and qualifications of the certified assessor as set forth in the proposed regulations. DTSC states, in 69505.1.(e), that “each AA completed on and after the date that is two (2) years after the effective date of these regulations shall be performed by, or under the responsible charge of, one or more assessor(s) certified under article 8 for the appropriate product type or industry sector.”

As set forth in, Article 8 “Accreditation Bodies and Certified Assessors,” of the proposed regulations, DTSC is under the mistaken notion that mere academic training can provide enough knowledge for a person to be able to either conduct or lead a robust alternative assessment. Two (2) years professional experience is not enough to be fully aware of the intricacies of formulating consumer products, and personal care products in particular, and post-graduate work in the performance of AA’s just cannot substitute for the two (2) years of professional experience. Significant experience in the laboratory is typically required for a formulator to know how to develop formulations that are stable and safe for several years, provide the benefits expected by consumers at a cost that they can afford, and then apply that to new ingredients. Five (5) – ten (10) years of experience working as a formulator or

processing engineer in a company making consumer products should be the minimum experience required, along with significant experience and training in project management. Global companies may also not have the correct academic and accreditation requirements as required by DTSC; global companies will likely have to rely on global formulation teams based outside the United States. As such, the final regulations will need to have the requisite flexibility to accept the qualifications of certified assessors from around the globe.

The proposed Article 8 assessor training and certification programs are also far too ambitious. To successfully develop a product for the consumer market requires the melding of many different skills, including chemistry, chemical engineering, packaging engineering, microbiology, toxicology, environmental toxicology, manufacturing, quality, occupational safety, finance, consumer insight (psychology, for example), marketing and more. The requirement that one person, especially one with so little real experience in formulation chemistry, to show expertise in all these fields is just not realistic. Unilever has Ph.D's in many of these fields; they are experts in their respective fields and have many years experience and knowledge in that field, but not in other facets of formulation. Developing and bringing a safe and successful product to market is the result of the combined efforts of these experts plus years of experience in making it all come together.

For many global companies the AA's will be conducted outside of the U.S.; California must make it possible for assessors to come from any geographic location.

If a certified assessor is hired by a company to conduct the AA, that company also has to ensure that the assessor is bound by strict confidentiality requirements. The assessor, to do the job adequately, will not only have to obtain confidential information about formulations but also the manufacturing and supply chain capability of the company.

Unilever proposes that the role of certified assessor be eliminated in favor of developing a list of guidelines, or checkpoints, that need to be addressed when conducting an AA. When DTSC receives the formal AA reports, it can quickly ascertain whether the appropriate factors have been evaluated. Any training that is to be done should be given to DTSC staff who review the AA reports.

#### 69508.1: Qualifications for Accreditation Bodies

As noted above, academic knowledge in various fields, without significant experience in formulation, processing, or manufacturing consumer products does not provide enough knowledge to become accredited to train and certify assessors. In many cases those conducting an AA will have significantly more experience than the accreditation body, a case which could lead to significant issues when there are disagreements.

The proposed accreditation program is unnecessarily bureaucratic and will not provide better assessors, since company expertise will still be the tools that companies will use to determine better alternatives, as they have done for many years. The accreditation program proposed would be better suited to helping develop guidelines for conducting

an AA and to provide additional training to DTSC in areas where staff members are not already experts.

69501.2.(b)(1)(B) plus other relevant sections such as 69501.2.(b)(2)(A)(2) and 69505.5.(d)(3): Notification of Persons who purchased product

The regulation requires that the manufacturer of a Priority Product provide to DTSC “the name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months....”

This requirement is impractical, since we sell products to many retailers and distributors located outside California who in turn bring products into the state. A manufacturer thus is not in a position to know the name and contact information for all such persons in the state of California, since we do not sell directly to these people.

We recommend that DTSC eliminate this requirement to notify all those who sell the product in the state of California, as it will not provide any benefit to consumers and will not serve to advance the goals of the legislation.

## Conclusion

Unilever has a long history of providing safe, sustainable products to the consumers in California. Our brand names are major assets in signifying the value which we deliver to consumers, and we take great care in ensuring that we meet the consumer needs in a safe and sustainable manner. While we support the goals of the legislation, we want the regulation to provide the greatest opportunity for innovation without the interference of overly burdensome compliance measures.

If you have any questions regarding our statements, don't hesitate to contact me.

Regards,

Dr. Jack Linard  
Head Regulatory Affairs Personal Care NA  
Unilever  
800 Sylvan Avenue  
Englewood Cliffs, NJ 07632

201-894-6513  
jack.linard@unilever.com

|

## GCREgs@DTSC

---

**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Ron Christensen; Pam Sexton  
**Subject:** Question on SCP - A

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #A:

While you expect us to publicly comment on this regulation before September 11th, why is not the complete proposed Chemicals of Concern List provided for our public review?

Background:

On page 24 (of 78) in SAFER CONSUMER PRODUCTS Proposed Regulations, R-2011-02, at your weblink <http://www.dtsc.ca.gov/upload/SCPProposedRegulationsNoUnderlineJuly2012.pdf>, you have written (at lines 11 through 14) the following:

" § 69502.3. Chemicals of Concern List.

(a) The Department shall post an informational list of the chemicals identified as Chemicals of Concern under section 69502.2(a) on the Department's website within thirty (30) days after the effective date of these regulations."

Additional Comment:

We would expect to be able to read the complete regulation with all of its components, including an initial listing of identified explicit chemicals!

Respectfully submitted,  
Gary Valasek

-----  
[YOUR EMAIL in TEXT FORMAT]

Department of Toxic Substances Control  
July 27, 2012

Dear Regulations List Subscriber:

The Department of Toxic Substances Control (DTSC) has submitted a new rulemaking proposal to the Office of Administrative Law (OAL) for review and public comment. We are sending you this notification because you have expressed an interest in DTSC's rulemaking activities.

Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2011-02

Office of Administrative Law Notice File Number: Z-2012-0717-04

Public Comment Period: July 27 - September 11

The Public Notice and all related documents will be posted at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> and <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

-----

## GCREgs@DTSC

---

**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Ron Christensen; Pam Sexton  
**Subject:** Question on SCP - B

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #B:

What documentation is being published for public review (within the July 27-September 11 public comment period) that supports each of the chemicals on the initial Chemicals of Concern List?

Respectfully submitted,  
Gary Valasek

-----  
[YOUR EMAIL in TEXT FORMAT]  
Department of Toxic Substances Control  
July 27, 2012

Dear Regulations List Subscriber:

The Department of Toxic Substances Control (DTSC) has submitted a new rulemaking proposal to the Office of Administrative Law (OAL) for review and public comment. We are sending you this notification because you have expressed an interest in DTSC's rulemaking activities.

Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2011-02

Office of Administrative Law Notice File Number: Z-2012-0717-04

Public Comment Period: July 27 - September 11

The Public Notice and all related documents will be posted at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> and <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

-----

## GCREgs@DTSC

---

**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Pam Sexton; Ron Christensen  
**Subject:** Question on SCP - C

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #C:

What was the criteria to drop the number of Chemicals of Concern from ~3000 in October 2011 to ~1200 in July 2012?

Background:

Item#1:

Your 16-page document of 10-31-2011 found at

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf>,

provides on page 2 the statement that the "regulations establish an immediate list of Chemicals of Concern (~3,000)..." and

your 5-page document of July 2012 found at

<http://www.dtsc.ca.gov/upload/SCPProposedRegulationsChangesJuly2012.pdf>,

provides on page 1 the statement that "the list will include ~1,200 COCs.....".

Item#2:

An interesting example of the workability of chemical criteria is found in the Federal EPA TSCA at

<http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf>

where EPA has shown transparency and accountability in their process of handling Work Plan Chemicals.

Respectfully submitted,

Gary Valasek

-----  
[YOUR EMAIL in TEXT FORMAT]

Department of Toxic Substances Control

July 27, 2012

Dear Regulations List Subscriber:

The Department of Toxic Substances Control (DTSC) has submitted a new rulemaking proposal to the Office of Administrative Law (OAL) for review and public comment. We are sending you this notification because you have expressed an interest in DTSC's rulemaking activities.

Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2011-02

Office of Administrative Law Notice File Number: Z-2012-0717-04

Public Comment Period: July 27 - September 11

The Public Notice and all related documents will be posted at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> and <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).  
-----



October 11, 2012

**VIA E-MAIL**

Kryisia Von Burg  
Regulations Coordinator, Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Electronic submittal: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Re: Proposed Safer Consumer Products Regulation  
Comments from Valero  
Department Reference Number: R-2011-02  
(Division 4.5, Title 22, California Code of Regulations, Chapter 55)**

Dear Ms. Von Burg:

The Valero Companies (“Valero”) appreciate this opportunity to provide these comments regarding the Department of Toxic Substances Control’s (“DTSC”) proposed regulation for Safer Consumer Products (SCP), as posted for public comment on July 31, 2012. Valero owns and operates two refineries in the state of California with a combined throughput capacity of over 305,000 barrels per day and markets our products on a retail and wholesale basis through an extensive pipeline distribution system. Valero is one of the nation’s largest retail operators with a significant presence in California as well as 37 other states.

We strongly urge DTSC to provide a specific exemption and/or exclusion for all transportation fuels from the SCP regulation. The goal of the SCP regulation is to “create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.” Valero supports such measures when applied in a manner that recognizes both products that are already inherently “safe” and products that are handled to such an extent that risks are minimized to ensure product safety. The definition of “consumer product” currently used by the regulation is extremely broad and can be construed to include transportation fuels, thereby subjecting all refined fuels produced for use in California to the SCP alternative analysis and potential reformulation requirements. Valero contends that transportation fuels, for the reasons outlined below, are already regulated and managed to an extent that ensures product safety and minimizes chemical risks, obviating the applicability to the SCP rule. We further contend that the SCP regulation is an inappropriate tool to apply to such ubiquitous and fungible products as transportation fuels, as the scope of impacts would extend far beyond the refiner to the entire distribution infrastructure. Finally, Valero incorporates by reference the comments and recommendations submitted by the Western States Petroleum Association (WSPA) submitted on October 11, 2012.

**1. Transportation fuels are already heavily regulated/reformulated to ensure product safety**

Transportation fuels have been the subject of increasingly-stringent regulations since the 1990's that impact both the fuel formulation as well as how fuels are handled, shipped, and stored. For instance, fuels have been reformulated to reduce toxics through the following:

- MSAT (2007): Reduced emissions of benzene, formaldehyde, naphthalene, and other air toxics. Lowering the benzene content in gasoline and reduced evaporative emission from fuel containers.
- RFG (1995 and 2000): Required cleaner burning formulations to reduce smog formation and toxic pollutants.
- Tier 2 (2000): Reduced sulfur content of gasoline by 90%
- RVP and seasonal blending (1990): Reduced volatility of fuels to limit evaporative losses and limit ozone formation
- RFS 1 and 2 (2007) and (2011): Requires the use of specific volumes of renewal fuels derived from biogenic sources.
- Toxic Substance Control Act (TSCA): Regulations specifically geared towards identifying substances of concern, their use and distribution in commerce, and the subsequent regulation and/or prohibition thereof.

In the context of safety regulations, transportation fuels are governed by the following:

- DOT regulations prescribing truck, rail and ship loading and handling obligations
- PHSMA regulations prescribing pipeline movements of transportation fuels
- OSHA regulations prescribing safety requirements on fuel dispensing equipment

There are additionally many state and/or local requirements not listed here that are already in effect. Regulation of fuels under these federal programs continues, with some rules continuing to phase-in newer and more stringent requirements over time. In the aggregate, there are a tremendous number of regulations that not only dictate the composition of transportation fuels to limit toxics, but also the physical handling, shipping, and dispensing of such fuels, all with the common goal reducing risk to human health and the environment. Valero contends that "product safety" with regards to transportation fuels has already been well addressed and further regulation through the SCP process will not provide any additional benefits or further "ensure process safety".

**2. The definition of "Consumer Products" should be applied in a manner commensurate with the goals of the regulation**

In the context of the CPS, a very broad reading of the term consumer products appears to conflict with the goals of the regulation. The CPS regulation is clearly geared towards those "consumer products" for which more frequent and/or intimate contact is common, thus increasing any risk of potential exposure. Cosmetics, clothing, food packaging, carpets, house paints, and furniture coatings: all of these are substances for which direct use involves a high degree of physical contact and exposure. Transportation fuels, through the regulations cited above, are in a very different category of materials, with limited exposure pathways and extant safer product formulations. Given the magnitude of the undertaking involved in the CPS, it is in the interest of DTSC to focus resources on those products for which the regulations are designed by supporting a limited definition of "consumer products" that omits those substances which are already heavily regulated in this regard.

**3. Transportation fuels are primarily a natural occurring substance that present unique problems when reformulating**

Many typical consumer products owe their formulations to deliberate and specific processes that require the production and/or addition of certain chemicals. If formulation requirements change, either the process can be adjusted or different chemicals for feedstocks are purchased. However, many of the substances that would potentially be targeted by the CPS rule are naturally occurring in the crude feedstocks, which present limited options when reformulation is required. An increasingly complex arrangement of separation and conversion process units at refineries must be constructed in order to remove and/or convert material into something usable in the transportation fuel pool. This was a significant undertaking with MSAT compliance, requiring years of planning, permitting, and construction. With the bulk of toxics already regulated or even eliminated, the remaining options available to refiners become increasingly exotic and expensive. Valero contends that the limited scope of solutions available to further reduce specific substances in refining products will not prove cost effective and we urge DTSC to perform this cost-benefit analysis in light of the heavy regulations already in place.

**4. Applying this rule to transportation fuels will potentially have downstream “unintended consequences” beyond those considered by the regulation.**

If the proposed SCP regulation was applied to transportation fuels, the impacts would extend far beyond modifications to the refining process. The entire supply chain – pipelines, rail, trucking, terminaling, even to the extent of impacting motor vehicle performance – would potentially be affected.

- Cross contamination will be a significant consideration if any fuel specifications vary considerable from those in current CARB-BOB and CARB Diesel. This situation would require special handling not only for storage at the refinery (requiring additional storage tanks) but in all modes of transport and storage downstream. Trucks and rail cars would require either dedicated service to the new formulation or require cleaning when changing between formulations. Downstream terminals, who could potentially store CARB-BOB and conventional gasoline without cross contamination driving the product “out of spec”, would now need additional, dedicated storage to handle the new formulation. Building the infrastructure to maintain compositional integrity of an additional transportation fuel would require significant capital expenditures across the entire fuels industry from refinery to retail. Further, this infrastructure would require permitting and significant construction time beyond the manufacturers’ purview, creating significant delays in the overall execution of the goal of getting reformulated products to market.
- The impact on vehicle operations due to the transition from conventional to low sulfur diesel is well documented. In removing a portion of sulfur and aromatics from diesel, fuel leaks developed from some vehicles due to shrinkage of the O-rings/seals on fuel pumps and injectors. This was a largely unforeseen consequence of the transition to “cleaner” fuels and the impact on downstream equipment. Lacking a detailed understanding of the chemistry involved in the reformulation of fuels required under the SCP, similar unintended consequences are possible, particularly given how motor vehicles are designed with increasingly exotic materials under very specific operation condition. In order to prevent the possibility of similar scenarios occurring under the SCP rule, any potential fuel reformulations considered would require extensive testing and review with the engine manufacturers before execution at the refinery level. The current proposal does not contemplate this time-consuming and expensive testing phase, instead only requiring affected industries to submit plans on the process changes necessary to meet DTSC’s predetermined

formulation for toxics reduction. The end result would potentially be a significant disruption at the consumer level.

**5. The proposed rule is insufficiently defined to provide adequate comment opportunities to potentially affected industries**

While the SCP proposal outlines in detail the process of determining Chemical of Concern (COC), and the regulations of these chemicals thereof, the draft regulation fails to provide the details necessary to determine 1) which industry or business will ultimately be impacted by this regulation, and 2) what chemicals will be regulated. Lacking the regulatory definition of either the chemicals to be regulated or the industries that would ultimately be impacted, we contend it not possible for the public review and comment requirements of the regulatory process to be sufficiently observed under the law. The universe of businesses and chemicals that may be regulated is lacking any boundaries and conditions such that industry would know where and how to provide meaningful comments. This type of “open-ended regulation” circumvents public notice and comment requirements by drafting regulations lacking in the details necessary for industries to understand who and what is regulated. At a minimum, DTSC should provide the list of COCs with this draft regulation so as to afford affected parties an opportunity to identify, in a tangible and quantifiable way, if they could be affected under this rule.

**6. DTSC should provide clarification that “consumer products” cannot be construed to include materials outside of retail transactions**

The definition of “Consumer Products” used under this regulation is found in the Health and Safety Code Section 25251:

- (e) "Consumer product" means a product or part of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:
- (1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.
  - (2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.
  - (3) A device as defined in Section 4023 of the Business of Professions Code.
  - (4) A food as defined in subdivision (a) of Section 109935.
  - (5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).
  - (6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).
  - (7) Mercury-containing lights defined as mercury-containing lamps, bulbs, tubes, or other electric devices that provide functional illumination.

Valero contends that this definition of “Consumer Product” is so broad as to encompass the sale of materials and products outside the realm of retail transactions, to instead include wholesale and bulk purchases between industries. The implications of this broad reading are significant as they could include crude oils, intermediates, and other hydrocarbon materials purchased by refineries as feedstocks. Chemicals purchased in-bulk by refineries, necessary for industrial operations, would also be impacted. We highly recommend that DTSC tailor the definition of “Consumer Products” so as to clearly exclude potential misinterpretations such as these and instead focus the definition to those products available to consumers at the retail level only.

Valero strongly urges DTSC to revise the proposed rule consistent with Valero's comments. We contend that transportation fuels have already been reformulated and are safely handled under the current federal and state regulations to "ensure product safety", obviating the need to reassess fuels under the SCP. Providing an exclusion for transportation fuels will keep the execution of the SCP rule consistent with the intent of focusing on those products for which society has direct and regular contact. It will also prevent any unintended consequences of infrastructure overhaul and equipment incompatibilities at the consumer level.

We look forward to working with DTSC on further rule development and the promulgation of a final rule that is reasonable, technically feasible, and cost effective. Please contact me at (210) 345-4620 should you have any questions or need clarifications concerning our comments.

Sincerely,



Matthew H. Hodges  
Director, Regulatory Affairs  
Valero Companies  
210-345-4620  
[matt.hodges@valero.com](mailto:matt.hodges@valero.com)

## GCREgs@DTSC

---

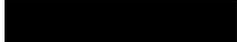
**From:** Mary Vernier <vernier.mary@gmail.com>  
**Sent:** Tuesday, October 09, 2012 7:52 AM  
**To:** GCREgs@DTSC  
**Subject:** California Department of Toxic Substances Control (DTSC) issued newly revised proposed regulations

Ms. Von Burg,

I am a small business owner, revenue in the \$5,000 range. My main product is Handcrafted Soap. The only way to make soap is to use Sodium Hydroxide (lye). I am concerned with the proposed changes and the impact that will have upon my business. The financial impact needs to be assessed at all revenue levels. Please contact the Handcrafted Soap Makers Guild organization in regards to work that has been done at the Federal level for our business. I am linking the HSMG web site below:

[Handcrafted Soap Makers Guild](#)

Thank you in advance for your consideration in this matter.

Mary Vernier of Mary's Green and Clean Handcrafted Soaps  




Submitted via Electronic Mail, October 11, 2012

California Department of Toxic Substances Control  
1001 I Street, P.O. Box 806  
Sacramento, CA 95812-0806  
[regs@dtsc.ca.gov](mailto:regs@dtsc.ca.gov)

**Re: Safer Consumer Products regulations (file number Z-2012-0717-04).**

Dear Sir or Madam:

The Vinyl Institute appreciates the opportunity to file these comments on proposed Safer Consumer Product regulations issued by the Department of Toxic Substances Control. The Vinyl Institute is an independent trade association representing U.S. producers of polyvinyl chloride resin and other materials that go into myriad vinyl products that people rely on every day.

In general we are writing to express our support for the comments filed by the American Chemistry Council (ACC). In particular, we are concerned about the costs, confusion, and potential disruptions to the businesses of our members, without significant public benefit, that may result if these regulations are finalized in their current form.

We do not understand the criteria by which DTSC will identify, prioritize, and evaluate hundreds of chemicals "of concern." Without more specific and objective criteria, chemicals that have proven safe and useful through long use in important products could be threatened with stigma, if not restrictions.

We urge DTSC to revise the regulations so as to adopt a clearer, more workable approach to reviewing chemicals in consumer products. As ACC has suggested, such an approach would identify chemicals that pose potentially significant consumer product hazards that have not been addressed by existing federal or state laws and regulations. These substances would be subject to priority review using established protocols. Any alternatives assessments deemed necessary would be subject to a comparably rigorous review process. Criteria should make clear how substances might "pass" such a review and should establish that substances that did pass would not be subject to further evaluation unless new information suggested a need.

We would be happy to discuss our concerns in further detail.

Sincerely,

Allen Blakey,  
Vice President, Industry and Government Affairs

# ALSTON & BIRD LLP

1115 11<sup>th</sup> Street  
Sacramento, CA 95814

916-498-3305  
Fax: 916-441-5449  
www.alston.com

**Maureen F. Gorsen**

**E-mail: [maureen.gorsen@aalston.com](mailto:maureen.gorsen@aalston.com)**

October 11, 2012

VIA EMAIL

[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

VIA MAIL

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
P.O. Box 806  
Sacramento, CA 95812-2806

Re: Comments on July 27, 2012, Draft Safer Consumer Product  
Alternatives Regulations

Dear Ms. Von Burg:

On behalf of Dr. John Warner, President and Chief Technology Officer of the Warner Babcock Institute for Green Chemistry ("Warner Babcock Institute"), we are pleased to submit the following comments regarding the Department of Toxic Substances Control's ("Department") proposed regulations to implement California's ground-breaking safer chemicals statute.

At the Warner-Babcock Institute, Dr. Warner is dedicated to the development of non-toxic, environmentally benign, and sustainable technological solutions for society. Dr. Warner believes that California has a tremendous opportunity to advance the development of green chemistry globally. Dr. Warner was honored and pleased to have had the opportunity to serve as Chair of the Green Chemistry Initiative Science Advisory Panel, which was convened in the fall of 2007 and finalized its recommendations and submitted its report to the Department in May 2008 (attached as Exhibit A.) Many of those recommendations were incorporated into the green chemistry laws that California enacted in November 2008. So now that the Department is poised to develop regulations to implement that statute, those initial recommendations should be revisited as many are absent from the current proposal.

The Department's proposed regulations are too heavily-focused on demand-side considerations, and give short shrift to supply-side considerations that are necessary to

bring the promises of a future that is benign by design. The alternatives analysis contained in the Initial Statement of Reasons does not indicate that much thought was given to supply-side considerations, nor alternative regulatory designs considered that could bring about the beneficial changes envisioned by the statute.

In the intervening years since the Science Advisory Panel issued its final recommendations, Dr. Warner has given this problem of the appropriate regulatory design much thought and reflection. Below is an outline of an alternative regulatory design that the Department should consider prior to adoption of the proposed regulation. He strongly believes this regulatory structure will accelerate the development of green chemistry and focus the efforts of industry and societal resources to those activities that will be of greatest benefit to the State of California and bring to fruition its ambitious aims to remake the way the world makes things.

### **Elements of Safer Chemicals Policy**

#### **A Regulatory Design to Accelerate Move to Safer Chemicals and Safer Consumer Products**

The outline below provides an opening discussion of five (5) elements of a safer chemicals policy. It is not intended to be prescriptive, but provides suggestions of a framework for moving forward.

##### **Element 1. Move from a list based system to an assay based system.**

For the past several decades, we have spent a great deal of time and effort focusing on identifying molecules of concern. Debate and controversy arises because people disagree on what the appropriate tests and methodologies should be. Much progress could be made if we focus our efforts on agreeing on what tests and assays we should be used to evaluate toxicity and environmental impact. If done correctly, this process will move us away from the “molecule by molecule” system towards an assay based system. By identifying the correct assays necessary to evaluate a product, we will significantly reduce cases of unfortunate substitutions. Having these criteria ironed out will provide industry with much needed guidance of what society deems as “safe.”

Without these criteria firmly in place it is difficult for industry to rationalize the significant investment necessary to invent safer alternatives. In our present system, the uncertainty of how new molecules will be evaluated, sometimes makes the investment in safer alternatives too risky. By identifying the various required assays, research organizations will be able to perform toxicology experiments during the early stages of research and thus be more cost effective and efficient.

Element 2. Move from a molecule based system to a product based system.

There are several tens of thousands of molecules in commerce. It is essentially impossible to evaluate or test them all. Many products or components of products consist of hundreds of different molecules. It is inappropriate to characterize a product as “safe” merely because it does not have a molecule that appears on a list somewhere. This method leads to unfortunate substitutions. The way to be better informed as to the impacts of a product on human health and the environment is to test the entire product (or subsets of components). This element is not designed to evaluate the *exposure* of any of the components or products to humans or the environment, but identifies that there exists within the product a compound that is giving a negative result on the assays identified in Element 1. The methodology of testing different physical states of materials will have to be addressed in the assay list developed in Element 1. If all the components of a product “pass” the assays identified in Element 1, then we can assume that based on the current level of knowledge, the product is likely “safe”.

Element 3. Identify and disclose hazardous materials.

When a product (or a component) fails an assay from Element 1, the company should be required to identify what assays the product failed. The company should document that a thorough alternatives assessment was performed to make sure the best available materials are being used. The company should perform an assessment of impacts in the (1) manufacture, (2) use and (3) disposal of the product and document plans to mitigate these impacts. If compelling evidence is provided documenting that the exposure to humans and the environment are appropriately controlled, the product should be allowed to enter commerce. In this case, the product should have appropriate labeling that identifies which assays from Element 1 have not been passed. The advantage of this approach is that company trade secrets are protected. No compound is ever identified, what is listed is that “some compound” in this product failed a certain assay.

Element 4. Focus on long term solutions.

When a product fails an assay from Element 1 and the company brings it to market with appropriate labeling, they should document their long term plans to help invent new safer alternatives. Depending on the size and nature of the organization, the level of involvement in inventing replacements should be commensurate. An organization within the Department should be formed to help companies articulate their technical needs and communicate these needs to the research community. This list of needs can help provide voluntary prioritization for various funding opportunities in both government and the private sector. Public workshops and conferences should be convened to alert the research and finance community of the needs and opportunities available. These workshops and conferences should bring together individuals describing

product needs and requirements, and people from toxicology and health sciences to discuss the mechanisms of harm so that new materials can be invented.

Element 5. Focus on jobs creation and workforce development.

The State should set up several “workforce development centers” to train high school graduates, 2-year college students and displaced workers. These people should be trained in competitive high-tech skills in the analytical/biotechnology industries. The hands on training should involve the execution of assays listed in Element 1. Sufficient oversight and redundancy will be necessary to ascertain quality. These centers should be fee-based with a plan to eventually become financially self-sustaining. Reduced rates can be provided to manufactures in state, providing an incentive for in state manufacturing.

With its groundbreaking safer chemicals law, California is in a unique position to play a global leadership role in creating the regulatory platform and infrastructure to stimulate the kinds of investment that are going to be necessary to bring about the invention of greener chemistries.

Five years ago, the Department commenced the Green Chemistry Initiative. The energy and enthusiasm for that Initiative has waned as the ideas that inspired so many have become mired in a regulatory bog that has lost its path. The Department has the opportunity to renew the energy and excitement for the promise and change that green chemistry can bring. To start fresh and reinvigorate industry in investing in a safer chemicals future, Dr. Warner urges the Department to immediately establish three committees described below and being in earnest a discussion on his five elements for a safer chemical policy.

Briefly, the suggested committees are described below.

Assay Committee: A diverse set of stakeholders to create a set of tests and assays that quantify toxicity and environmental impact. They should create the initial set of assays and describe the process of review and updating.

Compliance Committee: A diverse set of stakeholders to describe how testing protocols and data management will be certified and documented. They should create the initial plan and describe the process of review and updating.

Approval Committee: A diverse set of stakeholders to determine how materials that perform unacceptably in the assays should be handled. They should create the initial set of criteria describe the process of review and updating.

Dr. Warner would be pleased to work with the Department’s regulatory staff to develop the technical and regulatory language necessary to implement this alternative

Ms. Jones, DTSC  
October 11, 2012  
Page 5

regulatory design, or his assistance in developing the committees and working with stakeholders to develop this proposed five element framework.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Maureen F. Gorsen".

Maureen F. Gorsen

Attachments

Exhibit A: Green Chemistry Initiative Science Advisory Panel Final Report (May 2008)



October 9, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

The Water Quality Association (WQA), as a Green Chemistry Alliance (GCA) coalition member, joins many other associations and companies in opposing the state of California's proposed Safer Consumer Products Regulation, or Green Chemistry rules. We believe that the draft regulations are extremely unclear and a potential harm to consumers and the economy.

Our members, which include major manufacturers and sellers of water treatment products, have demonstrated an ongoing commitment to green products and environmental sensitivity. At the same time, they must have as much certainty as possible about regulatory schemes as they plan for the future.

The WQA respectfully submits the following comments relative to the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Alternatives Regulation of July 2012.

We believe the proposed regulations do not include a clear or science-based process by which the DTSC will ultimately select which chemicals and products it regulates. As written, it appears the regulation would also give the department full discretion to impose whatever remedies it chooses for violations. This would include imposing product restrictions to outright bans, or any approach the department decides on. It is hard to imagine companies being able to successfully plan new products with such uncertainty facing them.

We are concerned that our larger members could face significant costs associated with compliance, and smaller companies might find compliance simply impossible. No company, regardless of size, can determine from these regulations exactly how they will impact the ability to invest in, produce or sell a given product.

It is also troubling that the department's own economic analysis of the regulations concluded the impact to the state's economy is "unknown." In a time of economic struggle and high unemployment, it is critical that there be a clear understanding of the potential impact any regulations could have on jobs and the state's economy.

Safer products can be developed without placing new costs on consumers or endangering much-needed economic development in California. We believe the GCA has proposed workable, specific fixes to the key problems in the current draft regulations.

Thank you for your attention to this significant concern. As always, we look forward to working with policy makers and interest groups to find solutions that will work for everyone.

If you have any questions, please feel free to contact David Loveday at 630-505-0160.

Sincerely,

A handwritten signature in black ink, appearing to read "David Haataja". The signature is fluid and cursive, with a prominent initial "D" and a long, sweeping underline.

David Haataja  
Executive Director

*WQA is a not-for-profit association that provides public information about water treatment issues and also trains and certifies professionals to better serve consumers. WQA has more than 2,500 members internationally. WQA provides Gold Seal certification for products that remove a variety of contaminants. These products are tested according to independently developed standards of the highly respected ANSI (the American National Standards Institute).*



Western States Petroleum Association  
Credible Solutions • Responsive Service • Since 1907

**Catherine H. Reheis-Boyd**  
President

October 11, 2012

Via email (gcregs@dtsc.ca.gov)

Ms. Debbie Raphael (Draphael@dtsc.ca.gov)  
Director,  
Department of Toxic Substances Control  
1001 I Street,  
Sacramento, CA

**RE: Comments on Proposed Revisions to Safer Consumer Product Alternative (Green Chemistry)**

Dear Ms. Raphael:

The Western States Petroleum Association (WSPA) is a trade association that represents 27 companies that explore for, produce, refine, market and transport petroleum and petroleum products in the Western U.S. WSPA members have extensive operations in California and are directly affected by regulations that may govern the use, manufacturing, handling and disposal of petroleum products including crude oil, transportation fuels, solvents, coatings, and lubricants among many other products.

As you know, WSPA has been actively engaged in the policy discussions relating to passage of legislation that enabled the action by the Department of Toxic Substances Control (DTSC) as you initially proposed, and later the revised the draft Safer Consumer Product Alternatives (Green Chemistry) regulations.

We understand that the primary objective of the Safer Consumer Product Alternatives (SCPA) regulation is to incentivize responsible entities to identify, develop and implement processes that improve consumer products by designing them to be “safer” for both consumers and the environment, i.e., “benign-by-design”. However, based upon our review of the proposed regulations, Initial Statement of Reasons, (ISOR) and recent communications by the DTSC, the proposed SCPA regulations will likely create many unintended and adverse consequences that could frustrate achievement of this objective.

1415 L Street, Suite 600, Sacramento, California 95814  
(916) 498-7752 • Fax: (916) 444-5745 • Cell: (916) 835-0450  
cathy@wspa.org • www.wspa.org

We agree with the DTSC that a process that incentivizes incremental product improvement is more likely to be embraced by manufacturers on a voluntary basis and result in public health and environmental benefits. We have identified areas within the regulations that could be modified to improve the focus of the regulations.

### **Proposed Regulation is Vague and Undefined**

As currently proposed, the regulations provide no clear guidance to the agency or stakeholders. Specifically, the proposed regulations provide no criteria, standards or methodology for designating chemicals of concern (CoCs), prioritizing products, identifying of Alternative Analysis Threshold (AAT) values, conducting Alternative Analyses (AA) or procedures for identifying which alternative results in a “safer” product.

#### Lack of Clear Criteria, Standards and Methodology Limits Informed Planning

The DTSC has indicated that it seeks to utilize “market forces” as a primary means to further the “benign-by-design” objective of the SCPA. However, the lack of clear criteria, standards, and methodology in the proposed regulations limit the ability of responsible entities to make informed planning decisions to assure compliance with the regulation. In other words, lack of clarity on these key issues can inhibit responsible entities from accurately estimating environmental and economic costs and benefits that influence “market forces” and thereby slow the process of designing “safer” products, and in specific alternatives for individual products. This condition can leave consumers with fewer choices at higher costs which clearly is an undesirable market outcome.

#### Derivation of Alternative Analysis Threshold (AAT) Values

Another example of a lack of specific criteria, standards and methodology is how an AAT value is to be derived under §69503.5. We understand that the purpose of the AAT value in the SCPA program is similar to that of USEPA Region IX Regional Screening Levels (RSLs)<sup>1</sup> under the DTSC’s site mitigation and remediation program. We also understand that the intent is to improve administrative efficiency for both responsible entities and the DTSC by focusing the limited resources of both groups upon those conditions truly warranting more detailed evaluation, thus reducing total assessment and compliance costs for both groups.

However, §69503.5 provides no clear criteria, standards, and methodology for deriving an AAT value. Instead, §69503.5 (c)-(e) merely identifies an assortment of factors that the DTSC may consider in deriving an AAT value. How and which of these factors are to be considered is unstated. Thus, each AAT could be developed *de novo* for each priority product in an *ad hoc* manner.<sup>2</sup>

---

<sup>1</sup> RSLs were formerly known as Preliminary Remediation Goals or PRGs. See <http://www.epa.gov/region9/superfund/prg/> for more information regarding USEPA Region IX Regional Screening Levels.

<sup>2</sup> It seems that §69503.5(c)(2)(B) establishes the floor for the AAT value at the “minimum detectable concentration” of the CoC while the other listed factors are considered by the DTSC in unspecified *ad hoc* manner to derive several ceiling values for each factor. How the DTSC uses this information to derive the AAT value is unstated. Other questions are raised by the term “minimum detectable concentration” of the CoC as it is undefined. Does it mean the reporting level for a specific analytical laboratory for a specific chemical CoC in a specific media on a specific date?

In contrast to this approach, RSL values are derived in accordance with written guidance in a uniform and consistent manner that is transparent to stakeholders.<sup>3</sup> While the DTSC may intend to limit its expenditure of resources by substituting the limit of analytical detection for development of a product-specific AAT, failure to address the risk-based factors in §69503.5 (c)(3) will likely lead to stakeholder objections in the product prioritization process under Article 3 and petitions under Article 4 seeking development of product-specific AAT values. The limit of detection approach also lacks the rigor necessary to screen low risk products out of the regulatory process and therefore has little value to DTSC as a means of managing program resources and workload.

Recommendation: At a minimum, we suggest that the DTSC should consider developing AAT guidance to be used in both the priority product identification process and the petition process. Doing so will likely support the following goals:

- Enhance transparency to stakeholders as to how the DTSC shall derive AAT values;
- Permit “market forces” to work more efficiently by informing responsible entities of how the DTSC will implement this provision of the regulation; and
- Reduce unnecessary delays and reduce overall compliance costs incurred by both DTSC and responsible entities.

#### Designation of Priority Products

Another concern with the proposed regulations that is potentially exacerbated by the lack of criteria, standards, and methodology, is the discretion retained by the DTSC in the identification of priority products. We believe that the proposed regulations could result in the misallocation of resources caused by the nearly unlimited scope of products that maybe identified as priority products. This concern was recently expressed by responsible entities at the September 10 hearing in comments associated with products ranging in scope from very simple single component products such as bar soap, household cleaning liquids, etc., to very complicated multiple component products such as radios, computers, cars, jet airliners, etc.

All stakeholders would benefit from a clear indication by the DTSC of the types or characteristics of products that are not likely to be identified as priority products. Clarity will allow greater transparency of the DTSC’s decision-making process, while permitting more informed and focused input by stakeholders. Improved understanding of the language and intent of the regulations will encourage responsible entities to better allocate their resources to a limited number of identifiable problems as opposed to committing resources on theoretical concerns. Conversely, lack of clarity will discourage regulated entities from investing resources in green chemistry research and development, forestalling potential widespread public health and environmental benefits.

Recommendation: Improve the clarity of the regulations to indicate the method for prioritization of chemicals of concern. Improve the specificity, criteria, and the standards used in the agency’s decision-making process for prioritization of chemicals or products of concern.

---

<sup>3</sup>*Op cit.*

## **The Scope of the Regulation Does Not Match Statutory Authority**

The enabling statute prohibits the DTSC from 1) superseding the regulatory authority of any other federal or State of California agency, 2) duplicating regulations for product categories already regulated or subject to pending regulation or 3) adopting conflicting regulations for such product categories.<sup>4</sup> The purpose of these three separate requirements was to focus the DTSC's resources on protecting consumers and the environment from significant risks posed by consumer products to the extent that such risks are not already adequately mitigated by existing regulations. We do not see any of these three required principles reflected in the proposed regulation.

Also, perhaps of equal concern, are several provisions that seem to contemplate the very actions DTSC is expressly prohibited from taking under the statute. For example, the "End-of-Life" management requirements set forth at §69506.8 mandate a number of additional duties placed upon entities responsible for products that may supersede, duplicate, and/or conflict with existing End-of-Life management requirements. Specifically, many products, such as electronic waste (E-waste), paints, used tires, etc., are subject to existing End-of-Life regulations. It appears that the proposed regulations authorize DTSC to require manufacturers of products subject to existing End-of-Life regulations to develop and fund a separate program which would certainly duplicate, and likely conflict with, the current programs. Many of these products are currently regulated by Cal-Recycle, thus the imposition of such requirements would also clearly supersede Cal-Recycle's regulatory authority.

Another example of entire product categories that are subject to heavy regulation by a myriad of other state and federal agencies are transportation fuels, intermediates used in the production of those transportation fuels, and fuel additives. These product categories are already heavily regulated to address potential impacts to the environment, worker safety, and public health by the California Air Resources Board (ARB), local air pollution control districts, Office of Environmental Health Hazard Assessment (OEHHA), Department of Conservation's Division of Oil, Gas, and Geothermal Resources (DOGGR), U.S. Coast Guard, California Department of Fish and Game, Emergency Management Agency (EMA), State Water Resources Control Board (SWQCB), Regional Water Quality Control Boards (RWQCBs), DTSC, and the U.S. Environmental Protection Agency (USEPA). As you are aware, these agencies monitor and regulate for chemical composition, chemical characteristics, materials handling and disposal, as well as for exposure to ambient and worker environment.

The entirety of federal, state and local regulations demonstrate without dispute, that phases of product life cycles are regulated to protect human health and environment with a high degree of redundancy at both the federal and California state level, the effect of which is to minimize potential risks to human health, safety and the environment. As such, these are the types of categories which we believe H&S Section 25257.1 anticipates should be exempt from the pending Regulations.

We note that previous DTSC regulations also appeared to agree with this interpretation.<sup>5</sup> For example the October, 2011 proposed revisions, Section 69501 (b)(4)(A).1 and (A).2 make that clear:

---

<sup>4</sup>Health & Safety Code §§ 25257.1(b) and (c).

<sup>5</sup>As further evidence of the rigorous attention given to fuel regulation in California, your attention is also directed to the September 1, 2010 "Cal/EPA Fuels Guidance Document". It can be found on Cal/EPA's website at <http://www.calepa.ca.gov/biofuels/>. This document provides guidance to the public and regulated community on the scope

*“This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination:*

*1. Address the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and*

*2. Provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product. “*

We supported that approach.

Other examples where DTSC actions could be inconsistent with the prohibitions set forth at H&S Code §25257.1(b) and (c) involve the potential imposition of additional Regulatory Response requirements that extend into the workplace, to air emissions, discharges to water or land, waste management, hazardous materials management, or governmental specifications for many types of products, including, but not limited to, military equipment, building materials, vehicle components, fuels, etc. <sup>6</sup>

Recommendation: While the exemption in Article 6 is a step in the right direction, it does not sufficiently incorporate the prohibitions set forth at H&S Code § 25257.1(b) and (c). The proposed regulation improperly places the entire burden upon the responsible party to demonstrate to the DTSC that its actions supersede the authority of another agency, or duplicate and/or conflict with existing or pending regulations.

---

and breadth of fuels regulation in California. As indicated at page 4 of this document, the state agencies which contributed to the preparation of this guidance are the primary state agencies involved in the regulation of new fuels in California and which therefore regulate the health, safety and environment for Californians who buy fuels in the marketplace -- the Air Resources Board (ARB), the California Department of Food and Agriculture-Division of Measurement Standards (CDFA), CAL FIRE - Office of the State Fire Marshal (CAL FIRE - OSFM) and the State Water Resources Control Board (SWRCB).

<sup>6</sup>Some commenters at the September 10 hearing expressed concern regarding potential negative impacts to workers and nearby communities associated with perceived regulatory gaps for products manufactured, or stored in California, **but not sold in California** because the DTSC stated the proposed SCPA regulation does not apply to such products. Contrary to those concerns, there are no regulatory gaps for such products because: (1) the federal Occupational Safety and Health Administration and its California counterpart, Cal-OSHA, have jurisdiction over the workplace environment and have numerous existing regulations for the purpose of protecting workers;(2) the California Air Resources Board and the local Air Pollution Control Districts are responsible for regulating air emissions at such facilities for the purpose protecting the local community and environment; (3)the State Water Resources Control Board and Regional Water Quality Control Boards are responsible for regulating discharges to land and water that are also intended to protect the local community and environment;(4) the DTSC and/or local Certified Unified Program Agencies are responsible for hazardous waste management at these locations; and (5) local emergency response authorities typically address the management and storage of hazardous materials at such locations.

Therefore, we strongly recommend that at a minimum the DTSC incorporate the language from §69501(b)(4)(A) of the October 31, 2011 draft informal SCPA regulation as described above.

### **The DTSC Fails to Provide Adequate Protection of Intellectual Property, Confidential Business Information, and Trade Secrets**

The SCPA regulation objective of “benign-by-design” requires that significant investments be made by responsible entities to identify, develop and implement new processes and products, which in-turn necessitates protections for intellectual property, confidential business information and trade secrets. This protection is essential to ensure a return on investment that warrants the risk. Unless the investment in developing this information can be protected with a high degree of certainty, the regulated entity, will direct financial resources to lower risk investment opportunities. Failure to provide certainty with respect to protection of intellectual property, confidential business information and trade secrets will result in less investment in innovation, therefore, slower progress towards achieving the “benign-by-design” objective of SCPA regulation.

We note that this issue remains unaddressed in the current proposed regulations, despite many prior comments from stakeholders who pointed out that failure to adequately protect intellectual property, confidential business information, and trade secrets can imperil the very process DTSC is attempting to encourage. Having to seek trade secret protection remains unreasonably burdensome and whether it will be granted by the DTSC is too uncertain to reliably predict, thus creating a disincentive to invest in developing such information. Specifically, §69510 still requires responsible entities to provide far too much documentation and justification to the DTSC, yet the criteria for granting trade secret protection remains unstated in § 69510.1.

Recommendation: DTSC should focus upon protecting trade secret information and competitively sensitive information. Failure to adequately protect trade secret information in combination with the uncertainty surrounding the amount of discretion retained by the DTSC in its implementation of the SCPA regulation could chill the investment in product innovation and the development, implementation, and adoption of processes by responsible entities that will lead to the design of “safer” products.

### **Warranting Certified Third-Party Assessor is Unnecessary**

As explained in our prior comments upon an earlier version of the proposed regulations, we believe that the use of certified assessors as set forth in Article 8 is unwarranted. Specifically, the reasons offered by the DTSC to reject the status quo, i.e., “no certification”, in its ISOR<sup>7</sup> are inconsistent with the DTSC’s decision to maintain status quo for the first two years that the regulation is implemented –

---

<sup>7</sup>See p. 183 of the ISOR. According to the DTSC, adoption of these regulations without including a certification process for assessors would: (1) increase the amount of time required for DTSC’s reviews of the work that is submitted; (2) result in a lack of educational requirements and any person could prepare an AA; (3) result in there being no mechanism to widely disseminate advancements in technologies and manufacturing practices; and (4) result in a lack of consistency in quality and rigor in the preparation of AA. The theoretical negative impacts potentially attributable to these four points will be greatest during the first two years of implementation. However, such impacts should be largely mitigated by the time the certification requirements become applicable; thus, it is unclear why the certification requirements are necessary years after the regulation has been in effect.

precisely the period when both the DTSC and the regulated community are both likely to be least experienced with performing AA Reports. Furthermore, the proposed regulations create a process allowing third-party review and input to the DTSC on the adequacy of both the AA Reports and the proposed Regulatory Response.<sup>8</sup> Third-party review of the AA Reports is afforded via the proposed regulations while the reasons identified as warranting certification of assessors are simultaneously addressed via stakeholder input and DTSC review through the process described at §69506.1(b). Lastly, it is clear that DTSC retains the discretion and obligation to reject inadequate, incomplete, or erroneous AA Reports. This authority makes the requirement of the certified assessor program envisioned by Article 8 unnecessary as well as unduly burdensome.

Recommendation: We recommend the section on certification of assessors be removed because 3<sup>rd</sup> party assessors are unnecessary to assure the accuracy and adequacy of every AA Report, regardless of its complexity. We feel that the DTSC has the capability to ensure that AA Reports are accurate and adequate. Instead of requiring all AA Reports be prepared by certified assessors, we suggest that the DTSC become the principal reviewing authority for AA Reports and related documents, and if some type of additional scrutiny of an occasional complex AA is deemed necessary by the DTSC, it should be the exception, rather than the rule for all AAs. In any event, the DTSC review of AA Reports and all related documents, through whatever process is eventually chosen, must guarantee that intellectual property, confidential business information, and trade secrets are adequately protected.

### **Unclear if the Proposed Regulation Meets All CEQA Requirements**

Many commenters have expressed concern that the proposed SCPA Regulation has failed to satisfy all requirements of the California Environmental Quality Act (CEQA). WSPA shares those concerns as well.

Thank you for your attention. Should you have any questions, feel free to contact me or Mike Wang of my staff ([mike@wspa.org](mailto:mike@wspa.org); cell: 626-590-4905).

Sincerely,



Cc: Mike Wang  
Jeff Sickenger, KP  
Odette Madriago ([omadriago@dtsc.ca.gov](mailto:omadriago@dtsc.ca.gov))

---

<sup>8</sup>Specifically, §69501.5(b)(6) states Preliminary AA Reports, Final AA Reports, Abridged AA Reports will be placed upon the DTSC's website where stakeholders may review these documents. Thereafter, stakeholders may offer input to the DTSC on the proposed Regulatory Response, including comments upon the AA Report supporting the proposed Regulatory Response, per §69506.1(b). To the extent that any one or more of the four reasons identified by the DTSC as requiring certified assessors are present in an individual AA report, this process allows the problem(s) to be identified and properly addressed by the DTSC. The additional requirements for the certified assessor program in Article 8 are unnecessary, and therefore, unduly burdensome and wasteful of limited resources.

# TAYLOR

*Innovative Science. Applied Technology.*

**CORPORATE HEADQUARTERS**

W. F. Taylor Co., Inc.  
11545 Pacific Avenue  
Fontana, CA 92337  
800.397.4583  
951.360.6677  
951.360.1177 Fax

**ROBERT K. DDAMULIRA**

Vice President R&D  
209 Crown Lake Drive SE  
Dalton GA 30721  
706-712-5821 direct  
706-277-1363 Fax  
rddamulira@wftaylor.com

October 3<sup>rd</sup>, 2012

Deborah O. Raphael

Director

CA DTSC

1001 I Street, P.O. Box 806

Sacramento CA 95812

[draphael@dtsc.ca.gov](mailto:draphael@dtsc.ca.gov)

Tel: 916-322-0504

Fax: 916-324-3158

Re: Wood Flooring Urethane Adhesives Containing Uncured MDI

Dear Debbie:

Thank you for allowing us to present our position on the use of isocyanate containing urethane adhesive to the CA DTSC. We at W.F. Taylor are very concerned that isocyanate containing adhesives are being used in the installation of hardwood flooring products in residential and commercial buildings, an application that is uncontrolled and unregulated. In the light of the EPA action plan on Methylene Diphenyl Dissocyanate (MDI) and Related Compounds of April 2011 [RIN 2070-ZA15], we have compiled the following information to show the severity of the situation and convince the DTSC that MDI and TDI should be included on the CA chemicals of concern list and further that isocyanate containing urethane adhesives should not be used in the installation of flooring products.

We surveyed the MDI content listed on the Material Safety Data Sheets of six of the leading manufacturer of urethane based wood flooring adhesives and found that these products contain maximum levels of MDI that range from 1% to 25% (see table 1 below and copies of the material safety data sheet for these products can be forwarded to you or obtained from the manufacturer's websites). This concentration level of MDI in these urethane adhesives is equivalent to a range **10,000 ppm to 100,000 ppm**. These levels are much higher than the OSHA PEL for MDI which is **0.02 ppm** and ACGIH TLV-TWA for MDI which is **0.005 ppm** (OSHA Permissible Exposure Limits (PELs), 2012). In fact California's Office of Environmental Health Hazard Assessment has proposed a revised

reference exposure levels (REL) for MDI of  $0.7 \mu\text{g}/\text{m}^3$  (0.07 ppb) (California Office of Environmental Health Hazard Assessment (OEHHA), 2010). Urethane adhesive manufacturers claim that MDI has very low vapor pressure (with low volatility) and therefore there is minimal risk in getting the air concentration above the REL. While this is true, studies have shown that dermal exposure can trigger the same ill effects (including development of isocyanate asthma) (Bello, D; Streicher, R.P.; Liu, Y; Youngs, F; Cullen, M.R.; Redlich, C.A.; Herrick, C.A.; Smith, T.J., 2007).

It is our contention that installers and home owners (including their children) run the risk of skin exposure if continual use of these urethane adhesives that contain uncured isocyanates is not curtailed. We would further argue that the concentration level of MDI in these products is too high (over 500,000 times the OSHA PEL) to be considered harmless.

The Catalina Research Report (FC075 - January 2012) (Catalina Research, Inc., 2012) on the wood flooring industry reported that 922 million square feet of wood flooring was sold in the U.S.A in 2011. The Catalina report cites that about 50% of the wood flooring sold is engineered (Table 1-6 page 17). Assuming that 80% of this flooring is glued down and that MDI containing urethane adhesives have a 50% market share of this segment, the data shows that consumers will be exposed to an excess of **3.50 million pounds of MDI** (see table 2 below). According to the report, more than 50% of these floors were in residential replacement market (over **92 million square feet** – see table 2 below). Assuming an average renovation installation in a home of about 300 square feet, this means that over **300,000 homes** per year are exposed to these dangerous chemicals. The report further reported that over 37% of the wood sales were sold through the home centers and other retail outlets such as Home Depot, Lowe's, and Lumber Liquidators. Consumers who purchase products from these outlets are not regulated by OSHA. These figures support the point in the overview section of the EPA Action Plan on MDI that states that:

“This Action Plan focuses on the potential health effects that may result from exposures to the consumer or self-employed worker while using products containing uncured (unreacted) diisocyanates (e.g., spray applied foam sealants, adhesives, and coatings) or incidental exposures to the general population while such products are used in or around buildings including homes or schools.” (U.S. Environmental Protection Agency, 2011)

The fact that the majority of the installation is done in occupied homes (replacement jobs) makes potential exposure to families very real.

W.F.Taylor Co., Inc. urges the DTSC to list isocyanate containing urethane adhesives as “UNACCEPTABLE” for use in flooring installation. Additionally, W.F. Taylor wants to express our sincere concern that contractors and homeowners are currently being exposed to dangerous concentrations of isocyanates and request that the DTSC act promptly.

The adhesive flooring industry offers alternative installation adhesives that do not contain isocyanates. These alternative adhesive products have been in wide use throughout the world for over thirty years. W.F. Taylor Co., Inc. has had such products on the market for over 10 years and they include patented Meta-Tec Adhesives (patent number 6,706,789 B2) and MS (Modified Silane) Technology such as; Meta-Tec Taylor 2071, Meta-Tec MS Plus Advance Wood Flooring Adhesive and Meta-Tec MS Plus Resilient MBA Adhesive. These Taylor products are also certified by the Greenguard Institute (third party certifier) to meet stringent indoor air quality standards.

Sincerely,

*Bob Ddamulira*

Bob Ddamulira  
Vice President, Research and Development

**Table 1:**

| Manufacturer | Product Name    | MDI content  |
|--------------|-----------------|--------------|
| Bostik       | Bostik Best     | Up to 1.00%  |
|              | EFA             | Up to 1.00%  |
|              | BST             | Up to 1.00%  |
|              | ProCure         | Up to 1.00%  |
|              | TKO             | Up to 1.00%  |
| Mapei        | 975             | Up to 5.00%  |
|              | 980             | Up to 5.00%  |
|              | 990             | Up to 5.00%  |
|              | 995             | Up to 5.00%  |
| Sika         | Sika Bond T21   | Up to 5.00%  |
|              | Sika Bond T55   | Up to 5.00%  |
|              | Sika Bond T35   | Up to 5.00%  |
|              | Sika Bond T53   | Up to 5.00%  |
| Dri-Tac      | Dri-Tac 7300    | Up to 5.00%  |
|              | Dri-Tac 7400    | Up to 10.00% |
|              | Dri-Tac 7500    | Up to 2.00%  |
|              | Dri-Tac 7600    | Up to 2.00%  |
|              | Dri-Tac 1001    | Up to 5.00%  |
|              | Dri-Tac SMC     | Up to 2.00%  |
| Franklin     | GreenChoice 821 | Up to 5.00%  |
|              | Titebond 811    | Up to 5.00%  |
|              | Titebond 801    | Up to 5.00%  |
|              | Titebond 571    | Up to 5.00%  |
| Stauf        | PUM 955         | Up to 2.50%  |
|              | TFA 959         | Up to 25.00% |
|              | <b>Average</b>  | Up to 5%     |

**Table2:**

| <b>Installation by Wood Adhesives Type</b>                                                    |                    |
|-----------------------------------------------------------------------------------------------|--------------------|
| Total Sq. Ft. wood Installed in 2011 (Source - Catalina Research Report FC075 - January 2012) | <b>922,000,000</b> |
| 50% of Wood installed is Engineered Wood                                                      | 461,000,000        |
| 80% of Engineered Wood is Glued Down                                                          | 368,800,000        |
| 50% of Glued Down Wood done with Moisture Cure Urethane                                       | 184,400,000        |

---

**Moisture Cure Urethanes (MCU) Adhesives**

|                                                                                     |             |
|-------------------------------------------------------------------------------------|-------------|
| Sq. Ft. of Wood installed with Urethane Adhesives (50% of glued down installations) | 184,400,000 |
| 50% of Glued Down jobs done in residential replacement market (sq. ft.)             | 92,200,000  |
| Gallons of Urethane Adhesives used at 30 Sq. Ft. per gal                            | 6,146,667   |
| Pounds of Urethane Adhesives based on a density of 12.50 per gallon                 | 76,833,333  |
| Pounds MDI in Urethane Adhesives assuming MDI content of up to 5%                   | 3,641,900   |

## Bibliography

- OSHA Permissible Exposure Limits (PELs)*. (2012, MArch). Retrieved March 2012, from Occupational Safety and Health Administration: <http://www.osha.gov/SLTC/pel/>
- Bello, D; Streicher, R.P.; Liu, Y; Youngs, F; Cullen, M.R.; Redlich, C.A.; Herrick, C.A.; Smith, T.J. (2007). Skin Exposure to Isocyanates: Reasons for Concern. *Environ Health Perspect* 115.
- California Office of Environmental Health Hazard Assessment (OEHHA). (2010, April). Proposed Revised Reference Exposure Levels for Methylene Diphenyl Diisocyanate. Oakland, CA, USA.
- Catalina Research, Inc. (2012). *Wood Flooring, Catalina Report FC075*. Boca Raton: Catalina Research, Inc.
- U.S. Environmental Protection Agency. (2011). *Methylene Diphenyl Diisocyanate (MDI) and Related Compounds Action Plan [RIN 2070-ZA15]*. Washington DC: U.S. EPA.

## GCREgs@DTSC

---

**From:** Kristen Wick <kristenwick45@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 12:03 PM  
**To:** GCREgs@DTSC  
**Subject:** Regulations on dangerous chemicals

I strongly urge you to complete and enact strong rules for regulating potentially toxic chemicals. Now that the agency has identified these chemicals, the people of California need and want regulations that will eliminate public exposure to them. The chemical industry cannot be allowed to stand in the way of public health.

Thank you for your prompt attention to this matter.

Kristen C. Wick  




October 11, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, California 95812-0806  
E-mail: gcregs@dtsc.ca.gov  
Fax: (916) 324-1808

Dear Ms. Von Burg:

Re: Proposed California *Safer Consumer Product Regulations*

We prepared these comments based on activities and conversations with our partners and allies in the labor and environmental movements, as well as public and occupational health professionals.

Worksafe is a California-based independent non-profit dedicated to protecting people from job-related injuries, illnesses, and death. We advocate for protective worker health and safety laws and effective remedies for injured workers. In coalition with unions, workers, community, environmental and legal organizations, and scientists, we engage in campaigns to eliminate hazards and toxic chemicals from the workplace. We educate policymakers about the magnitude of workplace hazards and their impact on working people and communities, and propose public health-based solutions that focus on prevention. Many of our activities focus on low-wage immigrant workers and their experiences.

The labor movement and its public, occupational, and environmental health allies have a long-standing concern about the regulation of toxic substances in this country. With worker advocacy organizations like Worksafe, they have been key players in the fight to prevent and reduce work-related hazards and environmental pollution. For many of us, it has evolved into a vision of green jobs that are good for the environment and the people doing the work.

More and more regulatory and policy activities are moving in this direction. Its importance was pointed out in the first-of-its kind September 2012 [report](#) from the United Nations Environment Programme (UNEP). Commenting on

*Global Chemicals Outlook*, UN Under-Secretary General and UNEP Executive Director, Achim Steiner, [explained](#):

*.. the gains that chemicals can provide must not come at the expense of human health and the environment. Pollution and disease related to the unsustainable use, production and disposal of chemicals can, in fact, hinder progress towards key development targets by affecting water supplies, food security, well-being or worker productivity. Reducing hazards and improving chemicals management - at all stages of the supply chain - is, thus, an essential component of the transition to a low carbon, resource efficient and inclusive Green Economy.*

One of the most important global efforts is the Strategic Approach to International Chemicals Management ([SAICM](#)), [endorsed by](#) governments, public health organizations, workers' organizations and the International Labor Organisation (a tripartite -- government, employers, and unions/ workers -- international body). Its work includes the recent important agreements and discussions at the 3rd International Conference on Chemicals Management ([ICCM3](#)). In the context of a life cycle approach, the delegates (including some from the United States):

- reached a consensus decision that endocrine disruptors are a global emerging policy issue and the need for measures contributing to reductions in exposures or the effects of these chemicals, in particular among vulnerable populations;
- added nano materials and electrical and electronic products to the Global Plan of Action; and
- among many things related to electrical/electronic products, prioritized the elimination or substitution of hazardous chemicals, working on tools to help develop designs to reduce and eliminate the use of hazardous chemicals in their production, and tools and information about safer substitutes for chemicals of concern.

Other international efforts to develop innovative prevention-oriented chemicals policies include:

- the [SubSport](#) portal (supporting companies to fulfill substitution requirements of EU legislation);
- the International Chemical Secretariat ([ChemSec](#)) and its Substitute It Now ([SIN](#)) list;
- [Clean Production Action](#), an NGO based in Canada and the United States that has done groundbreaking work with its [Green Screen](#), Red List, and [Healthy Business Strategies for Transforming the Toxic Chemical Economy](#) (showing how companies can plan and design products for better environmental and economic benefits, based on practical experience with a variety of multinationals); and
- chemical policy [plans](#) in China and India that refer explicitly to the progressive European Union's REACH regulation.

In the United States, the federally-funded National Conversation on Public Health and Chemical Exposures developed an [action agenda](#) saying: “(p)romising developments in alternatives analysis and ‘green chemistry’ offer new opportunities for healthier communities, as well as for innovation, greater efficiency, and financial benefit in the marketplace.” It calls on all levels of government to “promote the substitution of hazardous chemicals with less toxic alternatives,” removing policy barriers to the process.

The 2008–2009 [Annual Report of the President's Cancer Panel, Reducing environmental cancer risk. What we can do now](#) is a groundbreaking document prepared by an illustrious group of experts. One of their key points is that we know enough to act on various fronts to prevent and reduce occupational and other environmental cancers. They say that “safer alternatives” to many hazardous chemicals are urgently needed, recommending:

*“Green chemistry” initiatives and research, including process redesign, should be pursued and supported more aggressively, but new products must be well-studied prior to and following their introduction into the environment and stringently regulated to ensure their short- and long-term safety.*

We also have been inspired by [ChemHAT](#), a new chemical hazard and safer alternatives tool being developed by and for workers and the BlueGreen Alliance. The [Alliance](#) includes California-based unions that have been active in developing the electronic tool and other green chemistry/chemical policy activities, with whom we also work on these important issues (e.g., District 9 of the Communication Workers of America -- CWA -- and the United Steelworkers -- USW).

The October 10<sup>th</sup> report, [Counting up to green: Assessing the green economy and its implications for growth and equity](#), from the Economic Policy Institute is based on one released in March 2012 by the Bureau of Labor Statistics ([BLS](#)). The most recent one describes the economics and attributes of a “green economy” that goes beyond energy sector jobs, and does, or could, use tools like ChemHAT. (California has the most green jobs in the country in 2010 -- 338,400.)

The proposed *Safer Consumer Product Regulations* are keeping up with some of these developments and findings, presenting one ingredient in the quest for those green jobs. Yes, they are groundbreaking. More important, they are necessary.

**It is important that workers and workplaces are included in these rules.** First, the authorizing statute requires it. Second, workers and workplaces are found at every stage of a consumer product’s life cycle. Workers extract ingredients for these products, make them, use them, recycle them, and dispose of them. Workers run the water and waste systems that the materials

and their by-products can affect. Workers live in the communities whose air and soil can be contaminated with their ingredients and waste, particularly fence-line communities. As Lisa Cullen said in *A Job to Die For*:

*The workplace is the mother lode of all environmental contaminants and exposures ... Most of what leaches into our drinking water, contaminates our food and pollutes our air comes from workplaces, where it first damages workers.*

We bring that worker/workplace and occupational health lens to the *Regulations*. That is our focus in these comments. Wearing our hats as consumers and citizens, we also care about the environmental health aspects in the proposed rules. However, we expect our allies in environmental health and the environmental justice movement, and other public health advocates and practitioners, will use their particular knowledge of those topics to focus on them in their comments. We support their, and other, efforts to make these *Regulations* the best possible for the sake of California's economy, people, and environments.

Finally, we want to acknowledge our comments are influenced by the inspiration and leadership about occupational and environmental health provided by Barry Commoner, who died recently. Promoting integrated views of the world, one of his important contributions for the purposes of these comments comes from *The Closing Circle* (1971). It is the notion that corporations, government, and consumers need to be in sync with the "four laws of ecology":

- ✓ *Everything is connected to everything else.*
- ✓ *Everything must go somewhere.*
- ✓ *Nature knows best.*
- ✓ *There is no such thing as a free lunch.*

These four "laws" are key to healthy and green economies, communities, and workplaces. They underlie the *Regulations'* life cycle approach and its public health goals.

With this framework, our comments are divided into general and specific sections. They are in the attached document. Please let me know if you have questions about any of them.

Sincerely



Dorothy Wigmore, M.S.  
Occupational health specialist



## **Comments about the proposed California *Safer Consumer Product Regulations***

### **General comments**

These *Regulations* are needed. They are an important, and ground-breaking, first step towards a state with fewer toxic substances and healthier, greener and more economically-sustainable communities.

For the first time, consumer product manufacturers must formally answer a key question about their practices: “Is the use of this hazardous chemical necessary in my product?” The original statute says they must focus on inherent hazards in those products and their ingredients, not a risk assessment of individual chemicals. This also is the first time that chemical regulations in this country try to account for cumulative exposures, a key occupational/public health concern and long-standing demand from environmental justice communities. And this is the first time a U.S. agency has tried to build a comprehensive regulatory structure that combines these approaches with requirements that manufacturers look for less toxic or non-toxic alternatives.

Like many of those concerned about the level of toxics in our lives, we urge DTSC to publish the final version of the *Regulations* as soon as possible, and start the process required in AB 1879. These regulations have gone through enough iterations. They are not perfect -- far from it. However, it’s time to “get on with it” and see how they work. It has taken far too long to initiate these important steps to reduce the toll of toxic substances in the state and to show the rest of the country, and the world, how California can once again be a leader of important public policies.

We also urge the governor and California state legislators to show leadership by supporting these regulations and the programs related to them in several ways. It should be their top priority to ensure that DTSC has the funding needed to implement this program effectively. Everyone involved agrees the Department does not have the resources required now; in fact, it has cut back on other pollution prevention activities to focus on this part of the Green Chemistry Initiative (GCI).

We also support the CHANGE coalition’s consistent feedback about the current paucity of information about the individual and combined effects of many of the 85,000 or so chemicals in commerce in the U.S. Paraphrasing their comments, we support a “no data, no market” requirement to close the

pervasive data gaps. This will level the playing field for all chemicals and the companies that make, import, and use them.

The proposed program limits DTSC's ability to require a minimum data set for all chemicals in commerce. This is a key shortcoming. Without comprehensive toxicity information, the Department's job is much more difficult than it should be. Therefore, building a "no data, no market" mechanism into California's regulatory structure is another key task for the legislature. We need laws, and related regulations and policies, to fill the data gaps outlined in the 2006 report to the legislature "*Green chemistry in California: A framework for leadership in chemicals policy and innovation*".

The questions "*Is this toxic substance necessary?*" and "*Is there a 'safer' alternative with no or limited health or environmental effects?*" are particularly important to us, given limited information about the toxicity of so many chemicals produced and/or used in California. They need to be asked about possible alternatives too, to avoid regrettable substitution.

We are pleased that some companies are taking these questions seriously and innovating their products and processes in the move towards a "green economy." Unfortunately, other industry voices have chosen the opposite response. They are calling for delays while raising inaccurate and exaggerated predictions about economic effects and cumbersome processes.

Those with long memories and historical views recognize the patterns. As EPA chief, Lisa Jackson, said in 2010:

*Today's forecasts of economic doom are nearly identical -- almost word for word -- to the doomsday predictions of the last 40 years. This "broken record" continues despite the fact that history has proven the doomsayers wrong again and again. ("Feeling heat on climate, EPA celebrates its past", [New York Times](#))*

Studies and reports that document her point -- and the possibilities that result from regulatory initiatives -- include:

- the Natural Resources Defense Council's recent analysis showing the "[delay game](#)" industry has played in response to EPA health assessments and regulation of chemicals;
- economic analyses of environmental and occupational health regulation, such as [Not too costly after all: An examination of the inflated cost estimates of health, safety and environmental protections](#), and [Setting the record straight: The Crain and Crain report on regulatory costs](#);
- the ground-breaking 2011 [report](#) showing we need regulations to protect people and the environment, and the improvements they provide;
- [examples](#) of the business case for policies like these *Regulations*, from the federal Occupational Health and Safety Administration (OSHA) ; and
- Worksafe's [Prevention pays](#).

Efforts to derail and dilute the proposed *Regulations* ignore the urgent need to reform the regulation and use of chemicals in California, and what is happening in the rest of the world (where many of the large companies complaining about the *Regulations* operate). They ignore the true costs of the current approaches that allow people, communities, and their environments to be guinea pigs for untested chemicals and the products in which they are found.

The *San Francisco Chronicle* editorial of September 30, 2012 made the correct point:

*Now, despite bipartisan support from lawmakers (for the 2008 authorizing statute), the pact is in danger of unraveling at the hands of the powerful chemical industry, which is lobbying every state official it can corner. To dilute this legal protection would be a disservice to California consumers.*

*... The (DTSC) needs to hear, emphatically, that these (potentially toxic) chemicals must be regulated and removed, and the **chemical industry can't be allowed to stand in the way of public health** (emphasis added).*

We agree and want to emphasize the importance of prevention and solution-focused policies and activities, especially for businesses:

*It is better to put a fence at the top of a cliff than an ambulance at the bottom. Companies are so bottom-line driven, prevention can be a hard sell, but it is always a better solution. (Director of Corporate Health Solutions for a Gary, Indiana hospital, *Indiana Business Magazine*, 2004)*

## **Specific comments**

We divided this section of our comments into what we support in formal version of the *Regulations* and where there are opportunities for improvements.

### **A. The *Regulations* are headed in the right direction**

We are pleased that occupational health is rightfully acknowledged as a public health issue in the proposed *Regulations*. This is consistent with the original statute, the life cycle approach it laid out, and the definition, understanding, and practice of “public health.” It also is important to include workers and workplaces as they are sometimes invisible players in this important effort. They are key at all stages in the life cycle of consumer products, including use, and often have higher exposures than most other consumers.

We also are glad to see that the *Regulations*:

- ✓ are part of the GCI, a broader and integrated effort to reduce the presence of toxic substances in the state and their effects on the environment, the public, and workers;
- ✓ are somewhat consistent with a green chemistry approach, at least emphasizing the inherent hazards of chemicals rather than the “risks” or odds they will have an effect, so that manufacturers are expected to develop products that are non- or less toxic (i.e., primary public health principles);
- ✓ use a life cycle approach that is a crucial framework for any modern and effective chemicals policy effort;
- ✓ advance chemicals policy activities by looking beyond individual chemicals to the cumulative effects they have with other chemicals, and to examining the hazards of the products in which they are used (which we want to ensure is expanded to include other factors);
- ✓ propose a realistic, unranked list of “chemicals of concern” based on lists that have made it through the prioritization processes of reputable scientific bodies and legislative authorities, covering many of the “hazard traits” of concern to workers and their employers (also see our recommendations for additions);
- ✓ define “sensitive subpopulations” to include “a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait or toxicological endpoint”, with recognition of workers as a group that has higher exposures (see our suggestion for the latter part, below);
- ✓ allow a realistic case-by-case approach to determine the amount of a chemical of concern in a product at which the Department will set a threshold point for regulatory action;
- ✓ include “places of employment” (i.e., workplaces) in the definition of reliable information about monitoring that shows there are exposures to chemicals (provided it meets a better definition of “reliable information,” as explained below);
- ✓ requires that those accrediting alternatives assessors understand occupational health issues, with some specifics; and
- ✓ have explicit language that health, safety, and environmental information or chemical identity cannot be a trade secret in hazard trait submissions (although we do not support the exception for proposed alternatives).

We have three recommendations to make these positive steps more effective.

**Recommendations:**

Update the chemicals of concern list every two years, as opposed to “periodically.”

Ensure the trade secret claims process is as transparent as possible; review the provisions in the Cal/OSHA *Hazard Communication Standard* ([http://www.dir.ca.gov/dosh/dosh\\_publications/hazcom.pdf](http://www.dir.ca.gov/dosh/dosh_publications/hazcom.pdf)) to avoid undermining those provisions. (We also support the more detailed CHANGE comments about this topic.)

Work with Cal/OSHA and the Department of Public Health's Occupational Health Branch (CDPH/OHB) to integrate efforts to protect workers and provide healthier workplaces. Reflect these results in guidance documents and related materials.

## **B. Opportunities for improvements**

We see opportunities for various improvements that are consistent with AB 1879 and a comprehensive framework to meet its goals. All our points are in this document, except for those about the alternatives assessment reporting process. We support CHANGE's position about the lack of transparency and oversight, key flaws in the proposed *Regulations*.

### **1. Make workers and workplaces more visible**

Overall, workers still are relatively invisible in the proposed *Regulations*. The name is used only twice and "workplace" is used once [besides the expectations about occupational health knowledge in s. 69508.1(a) (5)(G) (page 69, lines 10 – 11)]. Similarly, "occupation" or "occupational" turn up a total of four times, including the definition referred to in the cited lines.

As we said in an earlier letter, also signed by the California Labor Federation, the California Construction and Building Trades Council, and the District 9 director of the Communication Workers of America (CWA):

*Without more direct and clear language, workers and employers will be poorly informed about their rights and responsibilities related to the regulations and alternatives assessors may not account for occupational exposures.*

Whether or not the Department makes workers and workplaces more visible using our proposed language, they need to issue mandatory appendices or guidance documents explaining how workplaces/places of employment are expected to deal with these regulations. The documents should be prepared in a way that differentiates places where the products are manufactured from those where they are used, disposed of, recycled, or re-purposed. Occupational health and workplace considerations also need to be clearly stated for those doing alternatives assessments and Department staff overseeing submissions under these *Regulations*.

### **Recommendations:**

Emphasize the inclusion of occupational health and workplaces by:

- adding “(including occupational health)” to sections where DTSC and others must consider public health [e.g., after “public health” in S. 69502.2(b)(1)(C), page 23, line 34];
- adding “(including workers)” where DTSC and others must consider sensitive subpopulations [e.g., after “sensitive subpopulations” in S. 69502.2(b)(1)(B) 1, page 23, line 28];
- explicitly state that “adverse air quality impacts” include indoor air quality [s. 69501.1(a)(3), page 4, lines 37 - 39]; and
- define “consumer product” to be clear that it includes chemicals and products used on the job, including bulk purchases [s. 69501.1(a)(22)(A), page 8, line 32].

For information about how mandatory appendices can be used to accomplish this, see the Cal/OSHA [Hazard Communication Standard](#).

The broad definition of sensitive subpopulations [s. 69501.1(a)(58)] recognizes that occupational hazards often lead to greater exposures than those encountered in other settings (e.g., someone cleaning their own home). The exposures can be both higher and more frequent, making the hazard significant.

The wording is problematic, in that it is not the “nature of their occupation” but the job tasks or activities that are important. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. What they really do is what matters.

The definition also should be expanded to include women and men of reproductive age. Traditionally, women of child-bearing age are considered to be a sensitive sub-population. Unfortunately, this ignores long-time evidence that men’s occupational and environmental exposures (e.g., to lead, solvents, DES) affect their ability to conceive and have healthy children.

**Recommendations:**

Change the last phrase in this definition [S. 69501.1(a)(58), Page 13, lines 19 - 25] to read: “ .. greater exposures, or workers with greater exposures than other people, due to the nature of their occupation, accounting for tasks or activities”.

Add “women and men of child-bearing age” to the definition.

There are 12 elements in the end-of-life management plan. Responsible entities are expected to develop a plan that includes “the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse multimedia impacts.” Occupational health needs to be specifically mentioned here, as we and others have recommended.

## **Recommendation:**

Reword to read “.. the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse occupational health and multimedia environmental impacts.”

## **2. Don't exclude products made in California but not sold in the state**

Inclusion of s. 69501(b)(3) continues to perplex us. There are many arguments about why it should not be there. We present a few.

Workers are present at each stage of a chemical or product's life cycle. For most product uses, therefore, workers face higher and more intensive exposures than the general public. For example, the estimated 73,637 tons of general purpose cleaning products sold every day in California are used occasionally by household consumers, but daily by workers. Many workers face daily hazards from commercial products sold to consumers, such as paint thinners, solvent products, degreasers, paint strippers, carpet cleaners, and maintenance products. Workers involved in manufacturing these chemicals often face the most intense danger of all.

A life cycle approach includes the manufacture of products in California, regardless of where those products are eventually sold. As such, the *Regulations* should apply to all products manufactured in, stored in or transported through California, whether the products are sold here or not. The statute does not require this section. An upstream approach that captures products made in, stored in, or transported through the state is consistent with the GCI and the goals of AB 1879.

Other reasons to exclude this section include:

- Making products almost always contaminates the environment in some way, whether it is air, water, or land, unless pollution prevention strategies like these regulations are used. Otherwise, it is an invitation to more environmental contamination in the state, contrary to the rationale for the *Regulations*.
- It is unethical, as it effectively says you can make toxic products here or elsewhere, or ship them through the state, as long as you don't actually sell them in California.
- It is an economic disadvantage to companies making consumer products in California that send them out of the state, as well as sell them inside it.
- The rationale for this section in the *Statement of Reasons* refers to s. 25251, which defines several things, including a consumer product. That section does not refer to where the product is made or transported, nor does it exclude these activities as they involve products. The Department is inferring an intent for which there is no evidence in the enabling statute or the referenced documents.

- AB 1879 says the process in the regulations must consider at least three things, one of which is the potential for exposure to a consumer product’s chemicals. It does not say when this exposure must take place, again not excluding manufacturing, transportation, etc.
- It is unfair to put the onus on those providing comments about these regulations to find examples to back up concerns about this exclusion. As DTSC knows, it is extremely difficult to find up-to-date and accurate information about the range of chemicals and products produced, exported, and transported through this state. We have tried, without success so far. This is not surprising. A 2003 [analysis](#) by the Hazard Evaluation System and Information Service in the Department of Public Health (HESIS) found there are no tracking systems for chemicals or their products in California. CDPH/OHB currently cannot require manufacturers of a particularly toxic substance to reveal manufacturing locations so that workers can be warned of new hazard information about a chemical (e.g., diacetyl). (In 2005, AB 816 proposed this process; unfortunately, it was vetoed.)

Finally, this section is inconsistent with other parts of the *Regulations*. For example:

- “life cycle” is defined to include manufacture, transport and distribution [s. 69501.1 (a)(39)];
- the DTSC product prioritization process must consider the adverse effects of exposures during a product’s life cycle [s. 69503.2 (a) (1)];
- the same process refers to exposures during the life cycle, specifically naming “(m)anufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices” [s. 69503.2(a)(B)4.a]; and
- relevant factors in the second stage of alternatives analysis include those during the life cycle that make “a demonstrable contribution to one or more adverse .. impacts”, including occupational health [s. 69505.4(a)(1)(A)1].

**Recommendation:**

Delete s. 69501(b)(3).

**3. Expand the chemicals of concern list to include other serious hazard traits affecting consumers and workers alike**

More than 85,000 chemicals are currently available in the United States. However, the “list of lists” of “chemicals of concern” captures only a small portion of these mostly-untested substances. DTSC should augment the list with asthmagens, respiratory sensitizers, skin irritants, and skin sensitizers, all of which are already in the list of hazard traits in Chapter 54. These substances pose serious adverse effects for workers and consumers alike.

For example, a recent report for the National Institutes of Health, [Healthy environments. A compilation of substances linked to asthma](#), found 374 substances linked to asthma are used or present in buildings. A substantial number are found in products; 75 alone are in paints and adhesives, both of which are consumer products used in homes and other buildings.

Asthmagens take an expensive toll on individuals and society, including children. Asthma is the fourth leading cause of work absenteeism, costing almost “12 million missed or less productive workdays each year.” People with work-exacerbated asthma (WEA) report more days with symptoms, go for more medical care, and have a lower quality of life compared to adults with asthma unrelated to their job(s) ([American Thoracic Society](#), 2011). In Massachusetts, WEA cases are most commonly linked with cleaning products (13.2%); most of the hazard sources are either consumer products or common ingredients in them ([Asthma](#), Massachusetts Toxics Use Reduction Institute TUR and disease prevention fact sheet, 2012).

The 2010 report, [Asthma: A Business Case for Employers and Health Care Purchasers](#) advocates for replacing of “harsh cleaning chemicals” and other hazards. So too do California scientists, public health researchers and state public health officials (e.g., “[Primary prevention of occupational asthma: Identifying and controlling exposures to asthma-causing agents](#)” by Dr. Julia Quint and others, the state public health department’s [Strategic Plan for Asthma in California 2008 – 2012](#), and the [CDPH/OHB](#)). The American Thoracic Society agrees with them in its [official statement](#) about WEA.

Other respiratory sensitizers, skin sensitizers, and skin irritants also cause adverse public/occupational health effects that make people’s lives miserable and are expensive for employers, workers, their families and their communities. These hazard traits are common in workplaces and other consumer settings.

The National Institute for Occupational Safety and Health (NIOSH) estimates that more than 13 million U.S. workers can be exposed to chemicals absorbed through the skin. These [hazards](#) lead to skin diseases and allergies, and systemic effects ranging from acute effects and neurotoxicity to cancers and reproductive health effects. Again, the results are very expensive; estimated total annual costs are up to \$1 billion in 2002. The non-occupational burden of skin diseases increases the costs to society (not the manufacturer), even when the sources are limited to consumer products.

There are reliable lists for substances with these hazard traits from North American and European sources. As part of implementing the Globally Harmonized System of Classification and Labeling of Chemicals ([GHS](#)), the U.S. federal [Hazard Communication Standard](#) soon will require these hazard traits be named on “safety data sheets.” Other jurisdictions and organizations already recognize their importance.

**Recommendation:**

Expand the list of chemicals of concern to include asthmagens, respiratory sensitizers, skin irritants, and skin sensitizers. See Appendix 1 for our list of recommended sources. Note that most are ones that DTSC already plans to use for other purposes [e.g., s. 69502.2(a)(1)(B)].

**4. Change the language about causation**

DTSC has chosen to move away from AB 1879's use of "potential" hazards, exposure, and effects on sensitive sub-populations [see sections 25252 (a)(2), 25252 (a)(3), 25253(a)(2) and 25253 (a)(2)(K)], although the use of "potential" is legally defensible and should be binding. In fact, we question the legality of making this change.

Using the word "ability" puts an excessive onus on DTSC to show that chemicals and products cause harm to people and/or the environment. Given how quantitative epidemiological studies and chemical tests are conducted and interpreted, scientists and researchers interpret "cause" very conservatively. Epidemiologists traditionally want to be 95% sure they are correct, a level of proof far above that required in other arenas, including legal ones. Furthermore, they will argue until the cows come home about what is a "significant ability to contribute to or cause" a particular effect. This leads to fruitless arguments that have little to do with preventing and reducing the use of toxic substances.

Hence, it is important to retain the phrase "potential" to retain the GCI goals .

**Recommendations:**

Drop use of "cause" and replace with "potential" in the priority products prioritization factors [sections 69503.2(a)(1)(A) 1 - 3; page 25 line 32 and page 26, lines 7 and 16].

In s. 69503.2(b) 1 (page 27, line 27), replace "significant ability to contribute to or cause ..." with "the Chemical(s) of Concern in the product has the potential to contribute to or cause adverse...".

In s. 69503.2(b) 2 (page 27, line 31), replace "significant ability for .. to be exposed to the Chemical(s) of concern in the product in quantities that would contribute to or cause ..." with "ability for the ... to be exposed to the Chemical(s) of concern in the product in quantities that have the potential to contribute to or cause ...".

Elsewhere, use "reasonable likelihood to cause or contribute" or "reasonably likely to," instead of "ability to cause or contribute."

## 5. Re-consider the definition of reliable information

There is increasing evidence that single published papers may not be “reliable information.” This is particularly true of those sponsored by industrial or commercial concerns, as [UCSF researchers](#) and others have shown.

Single studies or case reports can point to the “canaries” (i.e., early warning signs or clues) of possible hazards, and help researchers, practitioners, and worker representatives make sense of their personal experiences, leading to further investigations. However, one published study with negative or very inconclusive results should not be grounds for discounting a chemical’s hazards. The biases reported in industry-sponsored or financed studies also need to be taken into account in any criteria about “reliable information” being used for public policy.

### **Recommendation:**

Consult with the UCSF researchers about how their findings in the [study](#) can provide a better definition of reliable information, one that accounts for industry bias and considers when a single study should be used.

## 6. Expand the factors considered in “cumulative effects”

We strongly support the use of cumulative effects in the *Regulations*. It is an important step to understand and account for the effects of chemicals. People are not simple slots into which one can put a chemical and understand its effects, without accounting for everything from the ergonomics of their activities, the temperature of their environment, and the hours they work, to gender, where they live, the food they can afford, and how they get around. For a simple example, we know that organic solvents increase the [hearing loss](#) of those in noisy environments.

More and more prevention-oriented efforts are trying to deal with the real-life integrated effect of specific chemicals, other hazards, and environmental surroundings (e.g., see the work of the Canadian Partnership Against Cancer, [www.partnershipagainstcancer.ca](http://www.partnershipagainstcancer.ca)). The [European Commission](#) is developing new approaches, and some California EPA activities, in particular the tools developed by OEHHA’s Cumulative Impacts and Precautionary Approaches Workgroup, show great promise. (DTSC should maintain its commitment to those efforts.)

### **Recommendations:**

Expand how cumulative effects are understood and considered to go beyond “other chemicals with the same or similar hazard traits.” Use language that commits DTSC also to consider other environmental

factors, such as, but not limited to, the built environment, socio-economic status, and nutrition.

For the best assessment possible, allow this to be done using qualitative and mixed quantitative-qualitative analysis.

## **7. Take a more preventive, public health approach to alternatives**

The proposed *Regulations* are supposed to be part of the state's GCI. Yet one overwhelming impression after reading them is the emphasis on containing or controlling exposures, not preventing the use of toxic substances in products. The latter is the most effective means to deal with a hazard, and the primary public health approach.

Containing and controlling are much less effective measures. Some of them (especially those that count on individual actions such as wearing protective clothing or following instructions about "correct" use) clearly only limit harm and do little to prevent adverse environmental or human health effects. (See Appendix 2 for a prevention triangle that summarizes this principle, based on the Belgian occupational health law.)

We fully support the hazard-based starting point of green chemistry and the proposed *Regulations*. We support the use of language such as giving "preference to regulatory responses providing the greatest level of inherent protection" [s. 69506(b), page 52, lines 10 -14].

We urge DTSC to use that starting point as the framework for its assessments and decision-making, and to put into practice the public health tenets of recognizing that controls or containment are interim and less effective solutions.

### **Recommendations:**

Rather than describing the process as considering alternatives to priority products to determine "how best to limit exposure to" a chemical of concern, explicitly state that it is about determining "how best to reduce the use of toxic chemicals" [s. 69501(a), page 4, lines 8 - 12].

Where there is talk of reducing exposures and effects, explicitly state that the goal is removal of toxic substances, re-design of processes, etc., and that other measures are less effective steps that may be necessary on an interim or short-term basis.

Use the prevention triangle in Appendix 2 as one tool in guidance, and related documents to explain the principles and goals.

## 8. Expand the definition of costs

In the second stage of alternatives analysis, s. 69505.4(1)(C) [page 43, lines 28 - 41], the current version of the *Regulations* tells responsible entities to “take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered.” Yet it defines a cost impact as an increase or decrease in a way that is contrary to the authorizing statute. It does not list indirect costs that are part of “the overall costs of those impacts to the state’s society” [s. 25255(2a) of AB 1879].

We are most familiar with studies about the costs of occupational illnesses and diseases. (There are similar studies about illnesses and diseases linked to environmental health and community health; again, we leave it to our environmental health colleagues and allies to provide that information.) These studies are few and far between, since most discussions center on what solutions cost, rather than what the “problem” -- the hazard and its effects -- costs.

These expenses often are externalized -- essentially given to individual workers, their families, communities and government agencies and (in the US) insurance companies that must deal with the wide array of personal, medical, and social costs attributable to occupational hazards. For example, UC Davis’ Paul [Leigh](#) reported in 2011 that:

*... medical and indirect costs of occupational injuries and illnesses are sizable, at least as large as the cost of cancer. Workers’ compensation covers less than 25 percent of these costs, so all members of society share the burden.*

Even leaving out important illnesses and diseases that could be related to chemical exposures, he found the USA’s [economic burden of occupational injury and illness](#) to be 516,149 deaths and cases that cost an estimated \$20.83 billion in 2007. Chemicals are a sizeable portion of occupational hazards, on their own or in combination with other hazards, and therefore of Leigh’s estimates.

### **Recommendations:**

Return to the original statute’s intention of “overall costs.”

Expand the definition of costs to include the externalized ones that others must pay during the life cycle of the product and its alternatives.

Include “occupational health and safety protection costs associated with use of the product.”

## 9. Recognize that monitoring data is hard to come by

Lists that form the basis of the “chemicals of concern” are changed on different timetables than studies and other reliable sources of information.

The reasons may also differ from those behind the proposed *Regulations*. Therefore, it is appropriate that DTSC have the responsibility, and ability, to identify other substances that should be on the chemicals of concern list.

Several criteria about updating lists [s. 69502.2(b)] are relevant to workers and occupational health practitioners: “sensitive subpopulations,” the ability to “contribute to or cause widespread” adverse public and/or environmental health effects, and exposure information.

Unfortunately, the exposure criteria may be difficult to apply. There is remarkably little accurate information available about what is sold and used in California homes, workplaces, and communities. There is even less monitoring of exposures. Monitoring methods have a history of being misused (e.g., area sampling applied to personal exposures) and the results misinterpreted. Therefore, “widespread” may be difficult to determine.

However, some occupational health regulations and enforcement activities require employers or Cal/OSHA inspectors to monitor for workplace hazards; in the latter case, the employers should have the results. Some employers include monitoring of hazards in their injury and illness prevention programs and other occupational health activities. This information could be used in efforts related to these *Regulations*.

### **Recommendations:**

Keep s. 69502.2(b) as is, provided the definition of “reliable information” is clarified, and the (illegal?) use of “cause” instead of “potential” is dealt with (see above).

Establish a transparent balancing of the lack of exposure information and need for details about exposure monitoring methods and results (to assess how relevant, accurate, and reliable they are) with the understanding of “widespread.”

Have transparent criteria for “widespread”. Use that criteria elsewhere in the *Regulations* [e.g., s. 69503.2(a)(1)(A)3].

Require responsible entities to submit information from relevant occupational hazard monitoring, including chemical names, number of workers and others exposed to the hazard, results and responses to the results. Work with Cal/OSHA to determine what information should be available, from whom, and how it could be used. Provide appropriate guidance based on the results.

## **10. Be cautious about the use of occupational exposure limits**

Section 69501.1(a)(6) (page 6, lines 4 - 5) talks about “exceedance of an enforceable .. standard relating to the protection of public health.” When applying this definition, DTSC should not include the standards known as occupational exposure limits (PELS or Permissible Exposure Limits in the

U.S.). They are out-of-date in terms of current toxicological information. Many offer “protection” for acute effects only, and the illusion that chronic effects are considered. And all too often, workers have symptoms and suffer acute and chronic effects when exposed to levels below these standards.

For example, in 2007 the state Office of Environmental Health Hazard Assessment (OEHHA) and the CDPH/OHB HESIS program looked at chemicals known to cause cancer or reproductive harm under Proposition 65. [More than 100](#) had no workplace permissible exposure limits (PELs) to protect workers from those effects. Most federal OSHA PELs have not been [updated](#) since 1971.

**Recommendation:**

In materials describing “adverse public health effects”, make clear that occupational exposure limits (OELs), and U.S. PELs in particular, are not enforceable standards that protect public health. Otherwise, deliberately exclude PELs and other OELs from the standards that are related to public health.

**11. Expand what DTSC considers in its regulatory responses**

Section 69506(c) sets out the principles for the department’s regulatory responses. We support having these in the *Regulations*, and recommend one addition that is in line with protecting public health and the environment.

As we and others advocated in a June 2012 letter, “just transition” should be a factor in regulatory responses. This idea came from Tony Mazzocchi, a union leader and early environmentalist. Inspired by the GI Bill (*The Servicemen’s Readjustment Act of 1944*), he called for a GI Bill for workers and their (often fence-line) communities. When they lose jobs thanks to the sunsetting of hazardous industries or substances, he wanted a “just transition” so they were not abandoned. They could be supported financially to learn and use new skills, particularly in green jobs in a green economy. The idea has been taken up by others (e.g., see the 2010 ILO report, [Climate change and labour: the need for a “just transition”](#)).

**Recommendation:**

Add consideration of a “just transition” to the regulatory response analysis: “The impact on communities (e.g., neighbors, employees, suppliers) connected to the manufacture of a product and ways to mitigate anticipated adverse impacts on those communities.”

**12. Ensure that public information includes “safety data sheets”**

The GHS (Globally Harmonized System) is changing how manufacturers present information about their products. Material safety data sheets

(MSDSs) will be called “safety data sheets” (SDSs). Currently, MSDSs are available for consumer products in some jurisdictions and often when those products are used in workplaces. (It is one requirement about providing information, set out in *Hazard Communication Standard* from the federal Occupational Safety and Health Administration -- OSHA -- and its California equivalent, Cal/OSHA.)

Sections 69505.5(e) (page 46, starting at line 35) and 69506.4 (page 54, starting at line 11) refer to information that should be provided. MSDSs or SDSs should be added, to be consistent with other state regulations and take advantage of existing information.

**Recommendation:**

Add “material safety data sheets (MSDSs) or safety data sheets (SDSs)” to the lists of information that must be provided.

**13. Make materials available in languages other than English**

The requirements in S. 69501.5 [page 19, lines 1 - 42; and page 20, lines 1 - 38] will enhance workers’ right to know about the hazards of products they use, and the Injury and Illness Prevention Programs ([IIPPs](#)) their employers must prepare to meet Cal/OSHA regulations.

Unfortunately, the information will be available only in English. This does little for the many people in the state with literacy issues in that language. The lists of chemicals of concern and priority products should be available in Spanish and other relevant languages. This also will assist retailers and other users. Other state government agencies already do this (e.g., Cal/OSHA, DLSE).

**Recommendation:**

Post information in Spanish when possible, and definitely when it is available in that language. Publish the lists of chemicals of concern and priority products in Spanish.

## Appendix 1

For asthmagens, skin irritants, and other sensitizers, see:

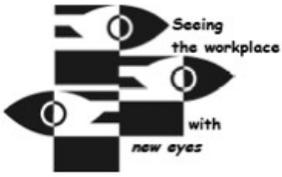
- <http://www.cdc.gov/niosh/topics/skin> (NIOSH information about skin irritants and sensitizers);
- <http://www.aoecdata.org/ExpCodeLookup.aspx> (Association of Occupational and Environmental Clinics -- AOEC);
- European Union EC 1272/2008 Annex VI: (1) Category 1 respiratory sensitizers; (2) Category 1 skin sensitizers:  
<http://esis.jrc.ec.europa.eu/index.php?PGM=cla> (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
- [http://www.cleanproduction.org/library/greenScreenv1-2/Green Screen v1-2 Supporting Lists.pdf](http://www.cleanproduction.org/library/greenScreenv1-2/Green%20Screen%20v1-2%20Supporting%20Lists.pdf) and search within for
  - 67 EU H-statement, H317 "May cause an allergic skin reaction",
  - 75 EU H-statement H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled",
  - 120 EU R-phrases R42 "May cause sensitization by inhalation",
  - 121 EU R-phrases R43 "May cause sensitization by skin contact",
  - 169 MAK Sensitizing Substances Sa (Respiratory),
  - 170 MAK Sensitizing Substances Sh (Skin),
  - 236 GHS-[COUNTRY] Category 1A (High Frequency of Occurrence), and
  - 237 GHS-[COUNTRY] Category 1B (Low to Moderate Frequency of Occurrence);
- National Institute for Occupational Safety and Health's 2009 *A strategy for assigning new NIOSH skin notations* (*Current Intelligence Bulletin 61*), and the chemicals which they have evaluated using this strategy ([http://www.cdc.gov/niosh/topics/skin/skin-notation\\_profiles.html](http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html))
- EU *Dangerous Substances Directive* (67/548/EEC), being replaced June 1, 2015 by GHS-related *Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures* (with current phrases): R21: Harmful in contact with skin; R24: Toxic in contact with skin; R27: Very toxic in contact with skin; R38: Irritating to skin; R43: May cause sensitization by skin contact; R66: Repeated exposure may cause skin dryness or cracking; S24: Avoid contact with skin; S28: After contact with skin, wash immediately with plenty of ...(to be specified by manufacturer) (see <http://osha.europa.eu/en/legislation/directives/exposure-to-chemical-agents-and-chemical-safety/osh-related-aspects/regulation->

[ec-no-1272-2008-classification-labelling-and-packaging-of-substances-and-mixtures](#))

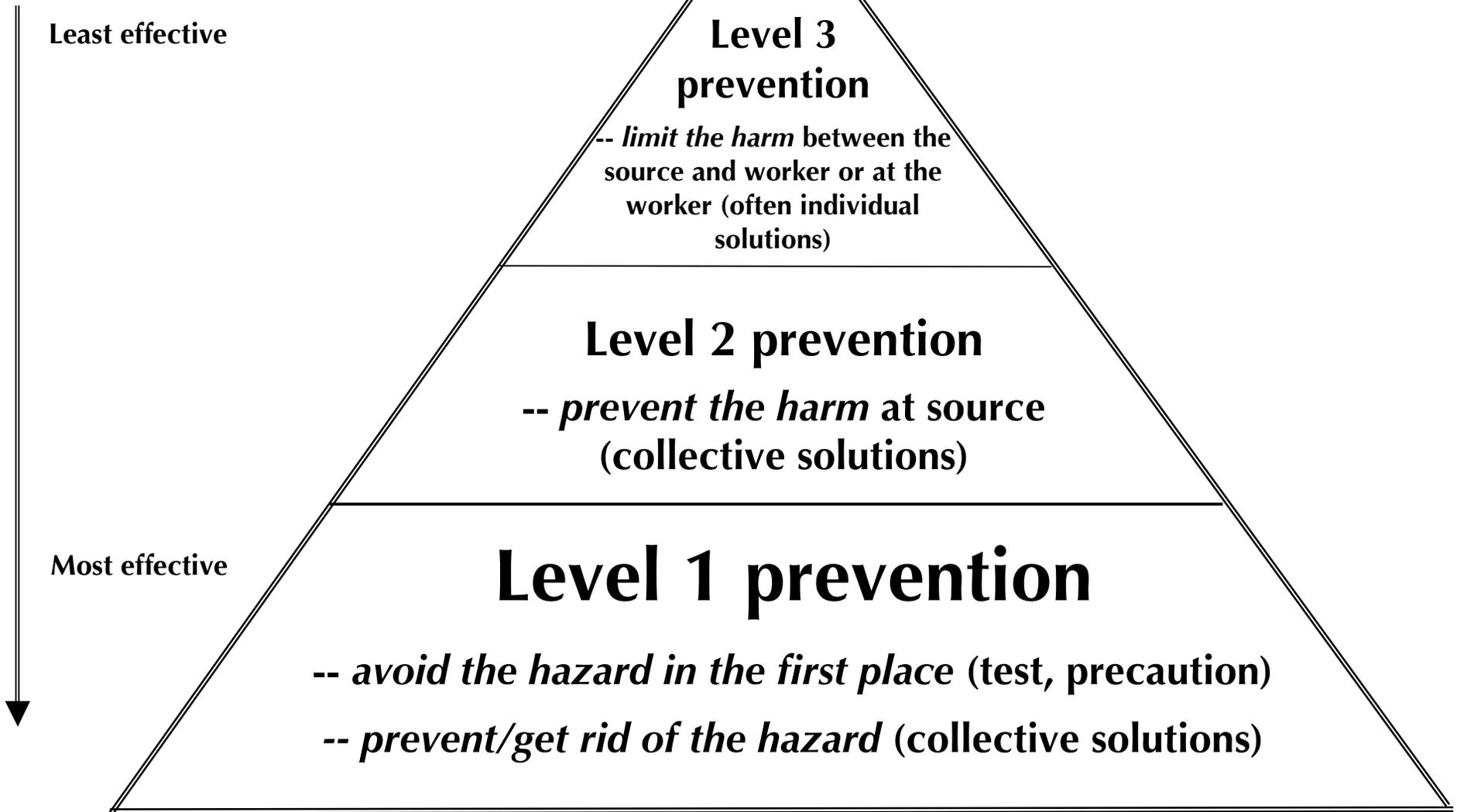
For other additions relevant to occupational and other settings, see Julia Quint's earlier recommendations:

- European Chemicals Agency *Candidate List of Substances of Very High Concern*  
([http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp));
- US EPA TSCA S. 5(e) *Existing Chemical Substance Significant New Use Regulation* (SNURs)  
(<http://www.epa.gov/oppt/existingchemicals/pubs/sect5a2.html>);
- US EPA *Existing Chemicals Action Plans*, chemicals for which EPA has developed plans (<http://www.epa.gov/oppt/existingchemicals/>);  
and
- US EPA TSCA S. 8(e) submissions  
(<http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2011/8ejan2011.html>).

## **Appendix 2 -- The prevention triangle**



# The prevention triangle -- principles for solving health and safety problems



\* *What happens if it's upside down (and you just limit the harm)? It falls over!*

# What's behind the prevention triangle?

The triangle borrows two concepts from the environmental movement.

**Informed substitution** is the principle about getting rid of toxic substances whenever a healthier and/or safer substance is available. Replacements are non-toxic or much less hazardous materials. It also describes changes about how things are done, using a different technology or re-organising the task to reduce or get rid of hazards. For more, see [www.cleanproduction.org](http://www.cleanproduction.org) and [www.turi.org](http://www.turi.org).

The **precautionary principle** -- "better safe than sorry" -- is part of several environment and health and safety laws. The idea is that there must be proof that something is not harmful before it is used, rather than using workers or the community as guinea pigs and only taking action when problems appear. For more information, see the European Environment Agency's <http://latelessons.ew.eea.europa.eu/>.

Health and safety specialists have used the word "controls" to describe changes or solutions that reduce exposure but don't get rid of the hazard. But their language is changing to emphasise prevention as opposed to putting up with a hazard. The Belgians offer a very useful way to do this, with levels of prevention (see <http://www.meta.fgov.be>).

**Level 1 prevention** is best. It gets rid of a hazard or avoids introducing a new one (when you use the precautionary principle). This is where substitution using non-toxic alternatives is most effective. Public health practitioners would call this primary prevention.

**Level 2 prevention** (a.k.a. engineering solutions or controls at the source) limits the hazard at its source (reducing its spread). The hazard is still there but ways to prevent harm include:

- ventilation enclosing the hazard, taking it all out of the workplace (without damaging the environment);
- enclosures to reduce noise levels;
- isolating the hazard or the people who may be exposed to it; and
- wet methods (with dusts).

**Level 3 prevention** only limits or reduces harm by putting something between the worker and the hazard source.

Changes or "controls" along the path between the hazard and workers, include:

- local ventilation that does not enclose the hazard;
- general ventilation;
- mechanical guards/devices; and
- some administrative controls (e.g. breaks).

At the worker (controls at the worker), Level 3 prevention includes personal protective equipment/clothing (PPE) and:

- some administrative activities (e.g. rotating workers, because it just spreads the hazard around and may even make it worse for some, especially if hazards to back are involved);
- work procedures, training and supervision, emergency plans;
- housekeeping, repair and maintenance programmes, and hygiene practices/facilities; and
- things to take care of yourself (especially when you're stressed).

These solutions are the least acceptable way to try to fix a problem, although there are times when they're needed.



October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the Writing Instrument Manufacturers Association ("WIMA"), I am making the following comments on the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

WIMA is the U.S. and Canadian trade association of the pen, pencil, marker and eraser industry. Our forty plus members sell writing instrument products throughout the United States. Approximately ten to fifteen percent of our members' sales are in California. Accordingly, the proposed regulation is of extraordinary importance to this industry.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We strongly recommend that DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe

that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

WIMA also expresses the following concerns about the regulation:

- We remain highly concerned that the proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).
- One of the most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation.
- It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we believe the Department must find a comprehensive solution, rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we are firm in our belief that the prioritization and evaluation process must be based on exposure and hazard, and it must avoid duplication and conflicting regulatory requirements.

DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. *This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemicals in that group of 1200+ which should rightly be identified as Chemicals of Concern.* No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.

WIMA supports a two step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals as "Chemicals Under Consideration." DTSC should next craft a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. *A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.*

- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.
- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

Finally, it appears that the State of California fails to evidence any concern of the competing financial impact to all involved, including state, business and the public it seeks to protect. An extensive and fair assessment of implementation, maintenance and program operation costs at all of the multiple levels impacted should be completed. In a seriously eroding business climate, it is wrong for the

State to feel empowered to run up exorbitant costs to be borne by manufacturers, distributors and, in the end, the citizens of California. The cost of such a program will simply be passed on to them in the elevated price of the products they purchase and the employment opportunities that leave when it is not fiscally conducive for a business to operate in California.

We appreciate your consideration of our concerns.

Respectfully submitted



David H. Baker  
Executive Director

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA .  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

## GCREgs@DTSC

---

**From:** David Bade <daveb@ampac-usa.com>  
**Sent:** Tuesday, October 09, 2012 3:04 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative - Proposed Regulations

Dear Regulations Coordinator Von Burg,

As a professional within the beauty industry, I wish to express my viewpoint on the proposed Green Chemistry Regulations. Our industry, including manufacturers, distributors, salon/spa owners and retailers, will be directly impacted by these regulations. As the regulations stand, there is too much uncertainty on the part of the DTSC on the economic impact on businesses both large and small, not only in California but throughout the United States.

The proposed regulations raise significant concerns for our industry, on issues such as trade secrets and confidential business information; excessive data submission requirements; product recall authority; retailer notification; a lack of scientific process to identify chemicals of concern; and many others.

I ask that you further postpone this initiative and publication of final regulations until the economic impact as well as other issues of concern can be assessed and any potential changes can be discussed at a future hearing.

Sincerely,

David Bade  


**From:** Joanna Abbott <joabbott903@comcast.net>  
**Sent:** Wednesday, August 22, 2012 4:37 PM  
**To:** GCREgs@DTSC  
**Subject:** Re: Support for a robust list of chemicals of concern as part of the Safer Consumer Products Regulations

Dear Director Raphael

As someone deeply concerned with the environmental and public health impacts of toxic chemicals used in commercial products, I wish to congratulate the Department of Toxic Substances Control (DTSC) on its proposed Safer Consumer Products regulations. They are a significant first step in changing how products sold in California are manufactured. These proposed regulations will help alleviate the threats to public health and the environment posed by toxics in consumer products.

At the heart of the proposed regulations is a robust list of Chemicals of Concern used in products that will be the focus of required alternatives analyses by product manufacturers. Since DTSC relied on internationally recognized lists of substances for which there is scientific evidence that they have the potential to cause harm, I fully support your Department's proposed list of approximately 1,200 Chemicals of Concern as a place to start. In future, as we learn more about the impacts of chemicals, including at low levels, it is likely that this list will have to expand. In the meantime, this proposed list will ensure that California addresses some of the most common environmental health threats, and provide manufacturers with guidance as to the chemicals they will need to find safer alternatives for in the years to come.

The Safer Consumer Products regulations represent an opportunity to protect public health and the environment while promoting innovation and economic growth in an international marketplace demanding safer products. This is an opportunity California cannot afford to pass up. I thank you and your staff for your hard work in developing this important program.

Sincerely,

Joanna Abbott

