

SAFER CONSUMER PRODUCT REGULATIONS  
**Public Comments to External Scientific Peer Review Reports**

<u>Page No.</u>	<u>Name of Commenter</u>
2	American Chemistry Council
8	American Cleaning Institute
11	American Forest & Paper Association
14	Amway
17	CA Council Environmental & Economic Balance
19	CA Industrial Hygiene Council
21	CHANGE
30	Consumer Specialty Products Association
44	European Union
46	Grocery Manufacturers Association
54	Rubber Manufacturers Association
65	SNR Denton
66	Unifrax
71	Western States Petroleum Association



January 4, 2013

Ms. Krysia Von Burg  
Regulations Coordinator  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, California 95812-0806  
E-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Re: American Chemistry Council Comments on External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products (R-2011-02)**

Dear Ms. Von Burg:

The American Chemistry Council<sup>1</sup> (ACC) welcomes the opportunity to provide comments on the External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products (R-2011-02). ACC is pleased that the Department of Toxic Substances Control (DTSC), pursuant to Health and Safety Code (HSC) §57004, submitted scientific portions of the proposed rule to external scientific peer reviewers. The following comments reflect observations, raise procedural questions, and in some cases provide supporting comments regarding the reviewers' reports.

### **General Comments and Observations**

While ACC is pleased that DTSC has proceeded to implement scientific peer review as required by HSC §57004, the peer reviewers' reports are not indicative of a holistic approach to an external scientific peer review of the proposed Safer Consumer Products Regulations. Instead, they at most rigidly conformed to the requirements of HSC §57004 requiring peer review of the scientific portions of the proposed regulations.<sup>2</sup> The manner in which DTSC framed, structured and conducted the scientific peer review process left much to be desired. Merely emphasizing portions of the regulations does not reflect a comprehensive view of the entire regulatory

---

<sup>1</sup> The business of chemistry is a \$760 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. 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.

<sup>2</sup> California Health and Safety Code Section 57004(d)(1), "[t]he board, department, or office submits the scientific portions of the proposed rule, along with a statement of the scientific findings, conclusions, and assumptions on which the scientific portions of the proposed rule are based and the supporting scientific data, studies, and other appropriate materials, to the external scientific peer review entity for its evaluation."



package. Since all of the scientific portions of the proposed rule interconnect, these interconnections must be science-based as well.

Regarding the four scientific portions selected by DTSC, ACC generally agrees with the selections: the use of chemicals lists to develop the list of Chemicals of Concern; the use of the initial product prioritization criteria in Article 3 to identify Priority Products containing Chemicals of Concern; Alternatives Analysis Threshold determination process; and, general usage and various definitions of the term “adverse impacts.” However, the proposed rule incorporates a number of additional scientific findings and processes, which DTSC’s scientific peer review did not address, specifically 1) the scientific portions of the proposed regulations pertaining to ascertainment of data reliability and study quality and the processes for integrating results across studies and 2) the scientific portions of the proposed regulations pertaining to evaluation of aggregate and cumulative risk.

When implementing the proposed regulations, DTSC will be conducting scientific evaluations of product lists (including the criteria listing), data and information on product composition, chemical hazard studies and exposure studies, and this will require Cal/EPA (both DTSC and OEHHA) to make scientific determinations of data reliability and study quality. For example, some studies may use inappropriate study designs (e.g., lack adequate control groups or use inappropriate numbers of subjects in each dose group). Other studies may rely on non-validated scientific methods or report results in such a manner that independent verification of results cannot be carried out. Regulatory determinations thus will require Cal/EPA to implement scientific procedures, such as those employed by the U.S. Environmental Protection Agency (U.S. EPA)<sup>3</sup> and Food and Drug Administration<sup>4</sup> or the European Chemicals Agency (ECHA)<sup>5</sup> to evaluate studies to determine the quality, reliability and adequacy of scientific information. In addition, where multiple studies exist, particularly if results across studies significantly differ, or where results from exposure modeling contrasts with exposure monitoring studies, Cal/EPA will need to integrate such results using a scientific process for determining the overall weight-of-the-evidence for a particular metric, effect or outcome. It is inexplicable for both DTSC and OEHHA to continue to ignore the importance of these scientific evaluation processes for determining the overall weight of the scientific evidence, which clearly is an integral part of the scientific evaluation procedures of the proposed regulatory process.<sup>6</sup> Both the U.S. EPA<sup>7</sup> and ECHA<sup>8</sup> have developed specific technical guidance<sup>9</sup> on weight of evidence determinations.

---

<sup>3</sup> <http://www.epa.gov/hpv/pubs/general/datadfin.htm>.

<sup>4</sup> Rulis AM and Levitt JA. (2009). FDA’S food ingredient approval process: Safety assurance based on scientific assessment. *Regul Toxicol Pharmacol*. 53: 20-31.

<sup>5</sup> ECHA REACH Guidance on information requirements and chemical safety assessment; [http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_en.htm?time=1259066690](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1259066690). Volume 3: Chapter R.4 Evaluation of available information.

<sup>6</sup> Comments of the ACC on Proposed Safer Consumer Product Regulation (July 27, 2012 (R-2011-02)) October, 11, 2012, p.2.

<sup>7</sup> See for example EPA’s Guidelines for Carcinogen Risk Assessment; <http://www.epa.gov/cancerguidelines/index.htm>.

<sup>8</sup> ECHA. How to report weight of evidence; [http://echa.europa.eu/documents/10162/13655/pg\\_report\\_weight\\_of\\_evidence\\_en.pdf](http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf)



Thus, this process is a scientific evaluation procedure which is well within the scope of the proposed regulatory process, therefore is subject to HSC §57004, and should be addressed as such by DTSC.

Additionally, there can be no doubt that both aggregate and cumulative risk are scientific evaluation procedures and thus fall within the scope of HSC §57004. Aggregate risk refers to the risks incurred by combined exposures to a single chemical across multiple routes (e.g., oral, dermal, inhalation) and across multiple pathways (e.g., air, food, drinking water). The U.S. EPA defines cumulative risk as the “risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes of exposure to a group of chemicals that share a common mechanism of toxicity.”<sup>10</sup> Both aggregate and cumulative risk determination procedures require scientific evaluation of hazards, scientific evaluation of exposures and scientific methods to combine risks spatially and temporally across routes and media (aggregate and cumulative) and across chemicals (cumulative). Clearly, DTSC’s exclusion from peer review of these scientific portions of the proposed regulations falls short of full compliance with HSC §57004.

### **Peer Review Design Procedure**

As articulated in HSC §57004, California specifies that agencies must enter into an agreement with certain institutions (National Academy of Sciences, the University of California, the California State University or other appropriate body) when initiating a peer review process of scientific portions of proposed regulations. However, the statute is not clear as to what criteria should be used to first identify potential peer reviewers and then to select the final peer reviewers and what role DTSC and Cal/EPA should play in these processes. For transparency purposes, ACC requests that DTSC disclose the criteria used to identify and select peer reviewers, including the processes used to address conflicts of interest, bias and to assure a balance of expertise and perspectives.

Although a number of the reviewers have previously held positions in a variety of capacities, all currently are affiliated with academia. One of the reviewers, Dr. Jennifer Sass is identified as affiliated with both George Washington University and the Natural Resources Defense Council. DTSC’s selection of a reviewer employed by an environmental non-government organization<sup>11</sup> should have, at a minimum, been balanced with an appointment of a scientist with industry toxicology and risk assessment expertise. Moreover, ACC believes it would have been

---

<sup>9</sup> ACC is not endorsing either the EPA or ECHA guidance. These citations are provided solely for the purpose of documenting that a weight of evidence evaluation is a scientific procedure. In fact, the National Academy of Science has been very critical of EPA’s approach to employing weight of evidence determinations, for example the NAS Review of the Environmental Protection Agency’s Draft IRIS Assessment of Formaldehyde (2011) at [http://www.nap.edu/catalog.php?record\\_id=13142#toc](http://www.nap.edu/catalog.php?record_id=13142#toc).

<sup>10</sup> EPA’s Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity, 2002, p. 2; [http://www.epa.gov/oppfead1/trac/science/cumulative\\_guidance.pdf](http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf).

<sup>11</sup> The National Resources Defense Council characterizes itself as “the nation’s most effective environmental action group;” <http://www.nrdc.org/about/>.



advantageous to have included reviewers affiliated with unaffected industries (e.g., pharmaceutical, pesticides), as well as experts affiliated with government entities. This would have provided both an industry perspective and a perspective on the scientific findings in terms of regulatory implementation. This lack of balance is of considerable concern and suggests that the procedures used to identify peer reviewers falls short of the best practices of such organizations as the National Academy of Sciences, which, for example, specifically speaks to the need for a balance of scientific perspectives in committee composition.<sup>12</sup>

### **Specific Comments on Reviewer Reports**

#### **a) Lack of Contextual Understanding**

As previously noted above, the reviewers focused on discreet portions of the proposed Safer Consumer Products Regulations, rather than evaluating the scientific portions in the context of the integrated whole. Subsequently, it appears as though a number of the reviewers are not familiar with the entirety of the proposed rule and therefore do not fully comprehend the interconnections of each provision. For example, Dr. Renn makes a suggestion that already exists in the proposed regulation, “there should be a sunshine clause that additional chemicals can be included in the list of new data or insights into toxic or eco-toxic consequences is available or the lists mentioned are augmented.”<sup>13</sup> Section 69502.3 Chemicals of Concern List currently provides a process by which chemicals may be added to the Chemicals of Concern List in order to reflect new data.

#### **b) Reliance on Limit of Detection**

Based on the peer reviewers’ reports, one controversial interpretation of the proposed regulation is now clear. As drafted, the DTSC proposal establishes the Alternatives Analysis Threshold (AAT) as the limit of detection of the chemical in question.<sup>14</sup> In prior conversations with both the Department, as well as other stakeholders, there had been some confusion as to how DTSC would interpret the basis for an AAT. It appears that the reviewers have confirmed the interpretation of the language of the Initial Statement of Reasons, “[t]he distinction between those Priority Products that are subject to the alternatives analysis and those that are exempt will

---

<sup>12</sup> The National Academies Policy on Committee Composition and Balance and Conflicts of Interest. [http://www.nationalacademies.org/coi/bi-coi\\_form-0.pdf](http://www.nationalacademies.org/coi/bi-coi_form-0.pdf), page 3. “...for example, it may be important to have an “industrial” perspective or an “environmental” perspective. This is not because such individuals are “representatives” of industrial or environmental interests, because no one is appointed by the institution to a study committee to represent a particular point of view or special interest. Rather it is because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee.”

<sup>13</sup> Renn, Ortwin, “Review Statement: Scientific Peer Review For Safer Consumer Product Regulations,” <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/13-Renn.pdf>.

<sup>14</sup> See reviews by Bennett, Christensen, Farland, and Locke, <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm>.



be primarily based on the minimum detectable concentration for the Chemical of Concern...<sup>15</sup> ACC is concerned that reliance on the limit of detection focuses DTSC's efforts on chemical elimination rather than safe use. This approach stands at odds with the statutory requirement that DTSC's regulations must, once chemicals of concern are identified in consumer products, determine how to best limit exposure or reduce the level of hazard posed by a chemical of concern.

### c) Critical Evaluations to Consider

ACC commends the handful of reviews that demonstrate critical, but constructive evaluations of the scientific portions of the proposed rule. In particular, ACC agrees with a number of points raised by Dr. Gray. For example, Dr. Gray first and foremost notes that alternatives assessment comes with the critical exercise of making science policy judgments and weighing competing outcomes. ACC also echoes Dr. Gray's concern regarding the establishment of a very large list of Chemicals of Concern. As Dr. Gray states, "I am concerned that the effort to cast a very wide net...by combining lists of chemicals developed for other purposes to determine CoCs will fail to appropriately focus this effort."<sup>16</sup> An important question related to the prioritization of both chemicals and products that Dr. Gray notes, which is also mentioned by other reviewers, such as Dr. Bennett, and Dr. Hattis, is how will exposure be apportioned to consumer products? Dr. Hattis goes on to state that "the initial unit of analysis/prioritization seems to be the chemical itself. However it is clear that the same chemical in different uses may have very different likelihood of being transferred to a person."<sup>17</sup> This peer review finding, which ACC agrees with, suggests that DTSC should identify, during the initial prioritization phase, the consumer product uses of "chemicals of concern" that are not otherwise regulated by federal or state law, or that have exposure and use patterns that may pose risks. Again, DTSC should focus its efforts where chemical/product combinations pose the greatest risks.

### Conclusions

Independent scientific peer review provides important feedback that needs to be evaluated and addressed when revising the proposed regulation, and when moving forward to issue a final rule. ACC is hopeful that DTSC will consider the fundamental questions and suggestions posed by the peer reviewers, prior to issuing the next version of the Safer Consumer Products Regulations.

Importantly, as required by HSC §57004, if DTSC disagrees "with any aspect of the finding of the external scientific peer review entity, it shall explain, and include as part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including

---

<sup>15</sup> Safer Consumer Products, Initial Statement of Reason, Section 69503.5 Alternatives Analysis Threshold Exemption, p. 104; <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>.

<sup>16</sup> Gray, George, Ph.D., "Review Statement: Scientific Peer Review For Safer Consumer Product Alternative Regulations;" <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/10-Gray.pdf>.

<sup>17</sup> Hattis, Dale, Ph.D., "Responses to Peer Review Points;" <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/11-Hattis.pdf>.



the reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.”<sup>18</sup> Therefore, ACC requests that, as part of the rulemaking, DTSC prepare and disseminate such an explanation.

Additionally, ACC requests that DTSC disclose the criteria used to identify and select peer reviewers, in an effort to provide more transparency to the process and in order to assure a balance of expertise and perspectives, should further independent peer review occur.

Furthermore, DTSC must fully comply with HSC §57004. Additional scientific peer review is warranted, since DTSC excluded from peer review critical scientific portions of the proposed regulations, 1) the scientific portions of the proposed regulations pertaining to ascertainment of data reliability and study quality and the processes for integrating results across studies and 2) the scientific portions of the proposed regulations pertaining to evaluation of aggregate and cumulative risk.

If you have any questions or concerns, please contact me at [Emily\\_Tipaldo@americanchemistry.com](mailto:Emily.Tipaldo@americanchemistry.com) or 202-249-6127.

Sincerely,



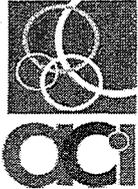
Emily Tipaldo  
Manager, Regulatory and Technical Affairs

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.Gusman-Aceves@gov.ca.gov](mailto:Martha.Gusman-Aceves@gov.ca.gov))

---

<sup>18</sup> California Health and Safety Code Section 57004(d)(2).





american cleaning institute®  
for better living

January 4, 2013

Krysia Von Burg, Regulations Coordinator  
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: External Scientific Peer Review of Proposed Safer Consumer Products Regulations**

Dear Ms. Von Burg:

The American Cleaning Institute (ACI) appreciates this opportunity to provide comments on the External Scientific Peer Review of the *Proposed Safer Consumer Products Regulations* released for public comment on November 29, 2012 by the California Department of Toxic Substances Control (DTSC or the Department).

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.

We understand that the Department was attempting to comply with Health and Safety Code section 57004 regarding submission of the scientific portions of the proposed Safer Consumer Product regulations to an external scientific peer review however we find the resulting effort deficient. In particular, we are disappointed by the lack of multi-sector representation in the reviewing panel, the narrow scope of the scientific elements of the regulation considered and the lack of supplemental direction for The Big Picture question.

The Department chose to select peer reviewers that are primarily professional academics. While the credentials of each reviewer is quite strong and individually each of them is well suited to represent the academic community, the development of the regulations would be better served by a peer review process that includes scientists and legal scholars with more practical experience implementing regulations or complying with them as a regulated entity. The Department failed to include regulatory scientists serving with competent authorities who are responsible for developing and implementing similar regulations (e.g. US EPA, US FDA, Environment Canada). We note that the OEHHA hazard trait regulations implementing SB509 included two peer

reviewers from US and Canadian federal agencies. The Safer Consumer Product regulations would benefit from review by similar scientists. Likewise, the peer review included no scientists from companies who are regularly responsible for complying with consumer product safety regulations. The Department could have easily reached out to companies in industry sectors that are exempt from the regulations (e.g. pesticides, pharmaceuticals) to draw on the experience of those individuals dealing with similar compliance issues.

The focus areas for the peer reviewers touched on only four of the many scientific portions of the regulation neglecting many of the definitions such as "reliable information" and "sensitive subpopulation", the criteria used by the Department to select the lists from which it would identify chemicals of concern and the criteria the Department will use to compare alternatives. The regulations would benefit from a more extensive review of all scientific elements.

The Department included The Big Picture question directly from the 2006 CalEPA guidelines. There being so many underlying scientific aspects to this regulation the reviewers would have benefited from some indication of the points of contention in the proposed regulation with a scientific aspect such as the use of certified assessors in the development of alternatives assessments, the use or weight-of-evidence in decision-making and the relationship between the conclusions of an alternatives assessment and the regulatory response.

Regarding the comments received by the reviewers, they were first asked whether the lists selected to establish what are to be considered Chemicals of Concern are scientifically appropriate. While the reviewers largely agreed with this premise, we believe this was not the critical question. The Department should have asked whether the criteria they used to select their lists were scientifically valid. Of course, since the Department has not selected those lists based on any specified principles our comment is academic. Likewise, the Department should have asked whether their criteria for prioritizing Chemicals of Concern as required by the statute were appropriate, and again, since those criteria do not exist, it is a hypothetical question.

There were substantial comments from the reviewers regarding the initial product prioritization criteria and the use of the key prioritization criteria to determine the Priority Products. Mr. Applegate noted that what is missing from the regulations "is a statement of a clear standard for placement on the list or not." Dr. Gray stated that "for most compounds the ability to rigorously address these concerns [appropriately prioritizing products considering aggregate and/or cumulative exposure and sensitive populations] is very difficult" and attempting to apply existing tools to address these prioritization factors "may be a recipe for confusion and contention." Dr. Renn stated "this number [of prioritizing criteria (40)] seems to be too high for being used to prioritize a large list of chemicals, second, many criteria are redundant, and thirdly, different classification principles have been used to complete the list." The reviewers seem to acknowledge the complex and opaque rubric that the Department has constructed for the selection of Priority Products. Most of the recommendations call for a more simple, transparent and workable approach that would protect companies intellectual property and confidential business information. We disagree with Dr. Sass who recommendation that market and sales information be made public. Individual companies' market and sales information is highly proprietary and should remain protected. However, product sales information is already publicly available and may be acquired through firms like Nielsen or SymphonyIRI.

Ms. Von Burg, DTSC  
January 4, 2013  
Page 3 of 3

Regarding the Alternatives Assessment (AA) Threshold, the reviewers were largely in agreement with the scientific principle of the Department's approach but there were a number of comments related to its practicality. Dr. Farland notes that "a variety of difficulties will be inherent in this endeavor" for example, what is the "minimum concentration of the COC(s) that can be detected in the Priority Product with available laboratory analytical methodology." Likewise, Dr. Locke states "the Department will be evaluating numerous CoCs in many Priority Products, and it is not clear that there are suitable laboratory analytical methodologies for CoCs under these diverse scenarios." Similarly, Dr. Sass commented on the difficulties associated with the Department's approach stating "I think this may be challenging for some chemicals or classes of chemicals." Drs. Renn and Gray also acknowledged the difficulties the Department will face in establishing the AA Thresholds. These comments mirror ACI's comments on several occasions that DTSC should take a more pragmatic and practical approach to establishing the AA Threshold keeping with Director Raphael's mantra of a workable, meaningful and defensible regulation. The Department's approach is scientifically defensible in theory but in practice may not be logistically feasible, resulting in a regulation that is ineffective and therefore not meaningful.

Several reviewers provided comments regarding the Department's definitions of "adverse" impacts. Dr. Farland recommended that the Department review a report that he co-authored from a Health and Environmental Sciences Institute (HESI) committee workshop in 2011 to discuss approaches to identifying adverse effects in the context of the NRC report *Toxicity Testing in the 21<sup>st</sup> Century*. Dr. Gray offered a number of specific and useful comments; for example, he stated that "adverse effects are actual outcomes" and noted those cases where the definitions do not reflect outcomes. Likewise, Dr. Renn suggested additional clarifications as well. These comments point to the need for further revision of the adverse impact definitions.

The reviewers' responses to The Big Picture question were largely unfocused, if they responded at all. As we noted above, we believe this is a reflection of the lack of direction from the Department on this question resulting in a missed opportunity.

Notwithstanding our criticism of the lack of experiential diversity among the peer reviewers, there were substantial comments from a number of the reviewers indicating that there is still a lot of work required by the Department in order to make the regulation practical, meaningful and defensible particularly with respect to the selection of Priority Products and the AA Threshold. We have commented numerous times on these regulations both formally and informally and continue to be dismayed at the Department's unwillingness to consider simple, workable solutions for implementation of this regulation. We look forward to the Department's next revision of the regulation with the hope that it will incorporate the comments of the many stakeholders and the peer-reviewers.

Sincerely,



Paul C. DeLeo, Ph.D.  
Senior Director, Environmental Safety



**American  
Forest & Paper  
Association**



**AMERICAN  
WOOD  
COUNCIL**

December 18, 2012

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

RE: Comments on the Scientific Peer Reviews on the proposed Safer Consumer Products Rulemaking

Dear Ms. Von Burg:

The American Forest & Paper Association (AF&PA) and American Wood Council (AWC) appreciate the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) on the scientific peer reviews on the proposed Safer Consumer Products (SCP) draft regulations.

AF&PA is the national trade association of the forest products industry, 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 men and women, exceeding employment levels in the automotive, chemicals and plastics industries. The industry meets a payroll of approximately \$50 billion annually and is among the top 10 manufacturing sector employers in 47 states.

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 over a 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.

## Alternative Analysis Threshold

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.” Professor Applegate of Indiana University commends DTSC for recognizing that the “benefits of recycling may outweigh the danger of contaminants” and this is exactly what a “sensible regulatory system must do, and the conclusion here is eminently justifiable.”<sup>1</sup> We wholeheartedly agree with Professor Applegate on this issue and strongly urge DTSC to take all appropriate steps to make sure the SCP is not ultimately counterproductive to recycling programs, especially in light of California’s new 75 percent recovery goal by 2020.

AF&PA and AWC agree with Deborah Bennett of University of California at Davis that when DTSC sets the alternative analysis threshold, it is important to consider the technical and economic feasibility of removing contaminants. We support Ms. Bennett’s recommendation that the threshold should be weighed against the “technical difficulties related to removing chemicals that are unintended contamination”<sup>2</sup> (e.g. in recycled materials) or naturally occurring chemicals (e.g. formaldehyde in wood). As we explained in our October 2012 comments to DTSC, AF&PA believes there should be 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.

## Regulatory Duplication

AF&PA and AWC agree with Professor Applegate that the DTSC needs to find the most efficient way to regulate and must be careful to avoid duplicating prior regulatory efforts.<sup>3</sup> AF&PA and AWC strongly believe the statute is clear 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.<sup>4</sup> 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. As an example, 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) and will be subject to the federal

---

<sup>1</sup> Applegate comments, page 5.

<sup>2</sup> Bennett comments, page 4.

<sup>3</sup> Applegate comments, page 1.

<sup>4</sup> 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.”

Formaldehyde Standards for Composite Wood Products Act or food contact materials which are already fully regulated by the U.S. Food and Drug Administration.

### **Chemical Lists and Prioritization**

AF&PA and AWC strongly disagree with Jennifer Sass of the Natural Resources Defense Council that the DTSC should consider even more chemical lists to determine chemicals of concern.<sup>5</sup> We agree with George Gray of George Washington University that the effort to cast a very wide net (lists of chemicals could be more than 3000 chemicals) “could fail to appropriately focus the effort.”<sup>6</sup> Further, we agree with George Gray that the prioritization criteria are too broad as it stands now, and the criteria need more specificity.<sup>7</sup>

### **Alternative Analysis Guidance**

AF&PA and AWC agree with George Gray that DTSC should allow as much flexibility in the alternative assessments as possible. The private sector will have a great deal of learning and experimentation as the methods and approaches to these alternative analyses will evolve.<sup>8</sup>

We appreciate the opportunity to comment on the external scientific peer review reports on the proposed Safer Consumer Products rulemaking. If you have any questions regarding AF&PA and AWC’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



Robert Glowinski  
President  
American Wood Council

---

<sup>5</sup> Sass comments, page 2.

<sup>6</sup> Gray comments, page 3.

<sup>7</sup> Gray comments, page 3.

<sup>8</sup> Gray comments, page 7.

7575 FULTON STREET EAST  
ADA, MICHIGAN 49355-0001

www.amway.com

January 4, 2013



Krysia Von Burg, Regulations Coordinator  
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))

### **External Scientific Peer Review - Safer Consumer Products Regulations Proposal**

Dear Ms. Von Burg:

Thank you for the opportunity for Amway to comment on the External Scientific Peer Review responses to California Department of Toxic Substances Control (DTSC) questions regarding the *Proposed Safer Consumer Products Regulations* as released for public comment on November 29, 2012.

Amway is a global business with nearly \$11 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 those 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 improve the Green Chemistry Initiative.

Unfortunately, we find the science review to be deficient in the scope of the questions, the responses and the limitations in the field of experts to which the questions were addressed. We understand that the Department was attempting to comply with Health and Safety Code section 57004 requiring scientific review of the Safer Consumer Product regulations as proposed to external experts. We particularly note the lack of experiential diversity among the selected reviewers and the very narrow focus of the questions posed. We were thus not surprised to find that the reviewers have failed to address the larger, practical issues of this regulation and its implementation.

The peer reviewers selected by DTSC are limited to theoreticians and primarily professional academics. These reviewers individually reflect substantial expertise on the topics referenced and represent the academic community perspective very well. However, there is a notable lack of scientific expertise in developing and implementing complex regulations. This could have been accomplished by including legal scholars with some practical regulatory

experience and regulatory scientists from competent authorities (e.g. US EPA, US FDA, Environment Canada or state regulators). Also, the peer review would have profited from participation by at least one scientist from industry who has responsibility for complying with consumer product safety regulations. DTSC could have secured valuable practical review from industry scientists that represent Green Chemistry exempt product categories (e.g. pesticides, pharmaceuticals).

The four focus areas for the peer reviewers seemed to plow some of the same ground that had been extensively addressed by the Green Ribbon panel and the public workshops. In our estimation, it would have been more profitable to consider larger questions such as guidance on the prioritization of the listed Chemicals of Concern. This would still have allowed endorsements of the list of list approach as were predictably received while gaining some additional insight on a path forward in selecting initial compounds. Similarly, the question that addressed the threshold for alternative analysis might have addressed the conditions under which the reviewers might have expected variation. Such changes in scope might have encouraged more informative responses that could have enhanced the regulation. In any case, a step back that allowed consideration of the practicality of this regulatory approach is needed before DTSC enters into implementation.

The sole big picture question repeated the 2006 CalEPA guidelines. This was far too perfunctory for new reviewers who would have profited by having DTSC indicate points of contention that have been raised in many discussions to date. For example, the role of certified assessors in the development of alternatives assessments or how weight-of-evidence might be used constructively in a complex regulatory context.

While our comments above reflect the most significant issues, Amway does have more specific issues regarding the review of each of the questions posed. However, only a few representative comments follow since detailed reaction is not likely to be helpful to the process of implementing the final regulation.

The question on deriving Chemicals of Concern (CoC) as a list of lists failed to elicit response on the appropriateness of assembling priority compounds from such diverse sources. We have no quarrel with reviewers' conclusion that such lists are a good starting point. However, we were disappointed that DTSC did not probe the issue of harmonizing those source lists into a prioritized CoC list. Since the statute expects a prioritization, we feel that an opportunity to elicit opinions on scientific bases for prioritizing from these experts and others would have been exceedingly valuable. In the case of Ms. Sass' review, she praised the inclusion of IARC 2A and 2B listed substances without noting the inherent distinctions between them and the relative priority those substances might have in a DTSC required AA.

At least, Mr. Applegate noted the regulations fail in providing "statement of a clear standard for placement on the list or not." Dr. Renn expands on the thought by asserting "this number (i.e. prioritizing criteria) seems to be too high for being

used to prioritize a large list of chemicals, second, many criteria are redundant, and thirdly, different classification principles have been used to complete the list." These reviewers highlight the inherent difficulties presented by the lack of clear priorities in the CoC list and potential minefield this leaves for implementation.

The Alternatives Assessment (AA) Threshold question failed to require reviewers to address the practicality of the proposal. Dr. Farland does speak to that issue in the following paragraph:

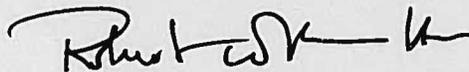
Likewise, the discussion of ***The presence or absence of a threshold dose response*** is rather simplistic. Issues such as dose-dependent transitions in response to exposure to toxic substances are now recognized. These may or may not equate to a threshold for toxicity. Additivity to background concentrations of both exogenous and endogenous concentrations of COCs must be considered. Most of the scientific community would argue with a default position that all carcinogens and mutagens will demonstrate thresholds. Similarly, the treatment of ***Cumulative exposures to other Chemicals of Concern that exhibit the same hazard trait*** leaves much scientific complexity unstated. Suggesting that cumulative exposures can be defined when they exhibit the same hazard trait and /or environmental or toxicological endpoint. This approach has been used in screening assessments but it ignores the fact that we understand modes of toxic action for substances which challenge the notion that things which exhibit the same toxicological endpoint will likely be additive in their toxicity. These are three examples that illustrate the concern that the listing of the principals in the regulation and the limited discussion in the ISOR will compromise the Departments credibility to carry out the AA Threshold assessment that they will be required to do and undermines the public and stakeholders confidence that the best available science will be used in the process.

This comment is instructive in that the whole solicited body of review there is insufficient consideration of the practical implementation of the rule.

We at Amway are very appreciative of the difficulty of developing and implementing such a visionary and comprehensive rule. However, we do feel that both the underlying regulation as proposed and the reviews that were submitted failed to address the fundamental principles elucidated by Director Raphael, "Is this regulation practical, meaningful and legally defensible."

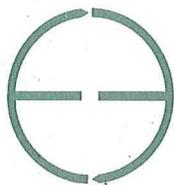
We look forward to continuing in participation toward a workable solution that meets those principles; and we appreciate the opportunity to comment.

Respectfully submitted,



Robert W. Hamilton  
Regulatory Policy Director, Amway

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  
Sara O'Neill  
George Plantka  
Art Pulaski  
Matt Rezvani  
Mike Roos  
Lanny Schmid  
Gerald D. Secundy  
Dan Skopec  
Don Solem  
Katherine Strehl  
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](http://www.cceeb.org)

December 21, 2012

Director Debbie Raphael  
California Department of Toxic Substances Control  
State of California  
1001 I Street  
Sacramento, CA 95812

*(Submitted via email)*

**Subject: Response to Public Availability of External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products**

Dear Ms. Raphael:

The California Council for Environmental and Economic Balance (CCEEB) is a coalition of California business, labor and public leaders that works together to advance strategies to achieve a sound economy and a healthy environment. Founded in 1973, CCEEB is a non-profit and non-partisan organization. We are disappointed that our request for an extension was denied. The importance and implications of this regulation are great and a reasonable approach is needed.

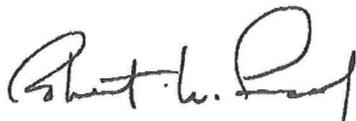
Examination of the peer review reports in detail takes time. CCEEB notes that you allowed each of the peer reviewers a formal response period from July 18<sup>th</sup> until August 30<sup>th</sup> to provide the noticed comments. The Department of Toxic Substances Control then waited three months to release these reports for public comment on November 30<sup>th</sup>. CCEEB also notes that these reports seem to be focused on policy as opposed to scientific rigor of the regulation. As such CCEEB would like to remind DTSC that its only true peer is the European Union's REACH program, which is the only operable program of its kind in the world. We have again attached their comments from the European Union, as we believe they are more pertinent than the ten policy reviews by academics being submitted for the record at this time.

It is unfortunate we will not have the time to comment on each report individually. We do hope moving forward DTSC will provide sufficient time for stakeholders to thoroughly review and provide comments on documents entered into the record or changes to the rule. We believe in a robust public process and often that requires consideration beyond the minimums set in statute.



If you wish to discuss this matter further, please contact Bob Lucas at 916-444-7337.

Sincerely,



Robert W. Lucas  
Waste and Water Quality Project Manager



Gerald D. Secundy  
President

Attachment

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  
Gordon Burns, Undersecretary, California Environmental Protection Agency  
Odette Madriago, Chief Deputy Director, DTSC  
Jackson Gualco, The Gualco Group, Inc.



*Advancing public policy to  
improve the health and safety  
of workers and the community.*

**CIHC Board:**

*President, Chris Laszcz-Davis, MS, CIH  
The Environmental Quality Organization, LLC  
Lafayette, CA  
(925) 330-1774*

*Vice-President, Ron Hutton, CIH  
Pacific Health & Safety, Inc.  
Mission Viejo, CA  
(949) 331-2732*

*Treasurer, Richard Bohrer, MS, CIH  
Adanta, Inc.  
Sacramento, CA  
(916) 705-2604*

*Secretary, Edward Klinenberg, Ph.D., CIH  
Northrop Grumman Information Systems  
Cyber & SIGINT Systems  
McClellan, CA  
(916) 570-4032*

**Directors:**

*Patricia Beach, MS, CIH  
Harris & Lee Environmental Sciences, LLC  
San Francisco, CA  
(415) 287-0056*

*Gloria Chan, CIH  
County of San Diego Environmental  
Health/OHP  
San Diego, CA  
(858) 694-2140*

*Nola J. Kennedy, PhD, CIH  
UCLA School of Public Health  
Los Angeles, CA  
(310) 794-7687*

*Samantha Chua, CIH  
General Atomics  
San Diego, CA  
(858) 455-2016*

*Howard Spielman, PE, CIH, CSP, REHS  
Health Science Associates  
Los Alamitos, CA  
(714) 220-3922*

**Alternates:**

*Joel Cohen, MPH, CIH  
The Cohen Group  
San Mateo, CA  
(650) 349-9737*

*Ain Graham, CIH  
U.S. Navy  
San Diego, CA  
(858) 577-8925*

*Jaime Steedman-Lyde, CIH  
Health Science Associates  
Los Alamitos, CA  
(714) 220-3922*

*Pamela Murcell, CIH  
KWA Safety & HAZMAT Consultants, Inc.  
El-Dorado, CA  
(530) 622-7196*

*Leo Vortouni, MPH, CIH  
Newport Beach, CA  
(949) 722-1253*

**Special Advisors:**

*Larry Gibbs, MEd, MPH, CIH  
Stanford University  
Palo Alto, CA  
(650) 723-7403*

*Deb Martin, MS, CIH  
Pacific Biosciences  
Menlo Park, CA  
(650) 521-8480*

**Sacramento Advocacy:**

*Catherine Barankin  
CIHC Legislative Office  
Sacramento, CA  
(916) 447-7341*

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 804  
Sacramento, CA 95812-0806

January 4, 2013

**Re: Comments on the External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products. Reference Number: R-2011-02**

Dear Ms. Von Burg:

The California Industrial Hygiene Council (CIHC) respectfully submits the following comments regarding the external scientific peer review reports obtained for the purpose of evaluating the scientific basis of the DTSC Safer Consumer Product Alternatives regulation.

Founded in 1990, the CIHC represents the occupational and environmental health profession in California and is affiliated with the American Industrial Hygiene Association (AIHA), a 10,000 member national organization, as well as the International Occupational Hygiene Association (IOHA), which represents the global community of Occupational Hygiene organizations in over 34 countries.

The CIHC concurs with many of the comments articulated by the scientific authors in their assessment of the regulation. Several of the discussion points are in line with comments previously submitted by the CIHC (see previous submittals dated 12/29/11 and 10/12/12). Of overarching importance is a general recommendation previously submitted by CIHC with regard to crafting a more focused regulation which concentrates on consumer product substances that pose true risks for human health and the environment (based on hazard, exposure, and probability of harm) as opposed to substances identified on the basis of "hazard traits" alone. The second overarching concern previously submitted by CIHC relates to the need for comparative analyses as determined by reliable scientific data and intended product use to ensure that unintended consequences are not introduced. Below are additional key points raised in the scientific peer reviews that are supported by the CIHC and worthy of re-emphasis:

**Product Prioritization Process:**

It is the shared view that the list of Chemicals of Concern (CoCs) is too broad and not well prioritized. The CIHC is in agreement that the criteria for priority classification is far too exhaustive. A more systematic approach should be established which is based on risk characterization. One such prioritization scheme offered by Ortwin Renn (in order of priority) is as follows: 1) threat to human health, 2) threat to environment, 3) hazardous traits that could lead to damages and 4) chemicals that could lead to harm if combined with other chemicals. This ranking should be based on hazard, exposure, and probability of harm.

**Availability of Data:**

The existing process for an effective Alternative Assessment is contingent on having quality data that is reliable, reproducible, and publically available. In alignment with previous CIHC comments, the scientific peer review authors have echoed the concern for availability of such data to determine safer alternatives. This is illustrated in the comment stating "The data required to demonstrate functional and technical equivalence is unlikely to be readily

available for a head-to-head comparison thus making the analysis problematic for a successful alternatives assessment process". It is unclear how the data gap issue will be addressed in the Alternatives Assessment process, particularly when working in the realm of limited data.

**Alternative Assessment (AA) Methodology:**

The use of Life Cycle Assessments (LCA) is widely supported in many of the peer review comments and supported by the CIHC in previous submittals to DTSC. It is rare that the LCA or Alternative Assessment (AA) process will yield results that evidence clear benefits across the spectrum of environmental and human health mid and end points. Thus, the AA process may involve weighing additional competitive functional and commercial parameters which rely on factors such as performance, availability, and costs, among others. As articulated by scientific reviewer George Gray, "In these cases value judgments must be made and thus cannot be strictly scientific as not everyone can agree on the relative importance of risk to public health vs. worker health vs. ecological effects". It is unclear how the regulation will address this issue. More emphasis should be placed on addressing the decision making process that will need to combine the use of scientific data and value judgments inherent in the comparative assessments process."

The CIHC is encouraged that many of the scientific reviewers' comments align with those previously submitted by the CIHC. It is our sincere hope that we can continue to assist in helping craft a process that is transparent and effective in endorsing products that mitigate adverse environmental and human health exposures to both workers and the general public alike.

Should you wish to discuss our comments further, please contact either of the CIHC representatives listed below.

Respectfully Submitted,



Ronald P. Hutton, CIH, AIHA Fellow  
President, CIHC  
P: (949)-331-2732  
[rehutton777@aim.com](mailto:rehutton777@aim.com)



Deb Martin, MS, CIH  
Special Advisor  
P: (650)-269-1512  
[debbusermartin@gmail.com](mailto:debbusermartin@gmail.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

COMMENTS ON THE  
EXTERNAL SCIENTIFIC PEER REVIEW REPORTS  
FOR THE SCIENTIFIC BASIS  
FOR DRAFT CALIFORNIA SAFER CONSUMER PRODUCTS REGULATIONS

January 4, 2013

CHANGE Coalition  
Californians for a Healthy and Green Economy

Californians for a Healthy and Green Economy (CHANGE) offers the following comments on the external scientific peer review reports for the Scientific Basis of the regulations for Safer Consumer Products.

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's key take-away from the external scientific peer review reports is that despite differences of opinion on some issues, there is substantial agreement among the peer reviewers that DTSC has proposed in its draft regulations a scientifically-based program to reduce Californians' exposure to toxic chemicals found in consumer products.

CHANGE would like to emphasize the widespread (but not universal) support among the peer reviewers for the scientific rationale for a large Chemicals of Concern (CoC) list.

Below, we point out specific points made in the external scientific peer review reports that CHANGE agrees with and that demonstrate the proposed program's scientific foundation.

### Re Nicholas Ashford

Dr. Ashford states the scientific portion of the draft regulations are "based on sound scientific knowledge, methods and practices."

We note that Dr. Ashford's comments don't align with the proper citations in the draft regulations. In that light, we attach a copy of his comments in which CHANGE has highlighted Ashford's specific suggestions. CHANGE supports the highlighted sections.

For example, Ashford writes that the CoC list and the Priority Products Prioritization factors have been assembled with "thoroughness" and "comprehensiveness." He supports inclusion of "occupational exposures, sensitive populations, neurotoxicity, endocrine disruption, and developmental effects" in the regulations, all of which are science-based concerns.

Ashford cautions against granting Alternative Analysis Threshold (AAT) exemptions to carcinogens, mutagens, teratogens, and endocrine disruptors. This supports the language in the DTSC draft regulations whereby DTSC will set AAT thresholds on a case-by-case basis, which CHANGE has argued is the scientific approach to take.

CHANGE also takes note of Ashford's comments on the economic impact of the proposed regulations, which is an area where he is deeply knowledgeable. He emphasizes that external costs must be factored into any economic analysis. Moreover, he stresses that positive economic benefits will accrue as a green chemistry industry grows. Both of these must be considered in economic impact analysis.

### Re John Applegate

John Applegate supports DTSC's reliance on lists of chemicals of concern prepared by

authoritative bodies as (1) an efficient use of the great scientific efforts expended by those bodies in preparing those lists, (2) an effective method of focussing regulators across programs, states and countries on the same problems, (3) an effective method of generating information and control strategies on common chemicals of concern and (4) aiding simplification of compliance strategies for regulated entities. Dr. Applegate also concludes that the lists DTSC has chosen are comprehensive, well considered and provide "as firm a basis as exists" for creating an initial list of chemicals of concern, particularly in view of the regulatory provisions for updating and for adding and deleting chemicals from the list. CHANGE agrees with these conclusions.

Applegate supports as sufficient and comprehensive the prioritization criteria used in evaluating adverse impacts and exposures of products and prioritizing products. CHANGE agrees with this. Dr. Applegate also supports the consideration of aspects of products that reduce or control exposure. CHANGE understands the impulse to consider these aspects during priority setting, but also cautions that assumptions about the effectiveness of control strategies, especially in view of full product lifecycles, have often proven erroneous and should not be permitted to undermine the essential thrust of the regulations, which is to motivate the development of safer products using fewer chemicals of concern.

Applegate expresses concern with DTSC's limited ability to obtain information about CoCs and products in a comprehensive or systematic way, calling it a "regulatory gap." CHANGE agrees that this is a problem, which could undermine the ultimate effectiveness of the law if not remedied as implementation proceeds. Dr. Applegate also notes that the regulations do not establish a clear bright line rule for defining whether a product will be classified as a Priority Product, and supports the approach of the regulations of relying on DTSC's professional judgment of all the competing considerations. CHANGE also recognizes this problem, which originates with the absence of such a standard in AB 1879, and agrees that it is incumbent on DTSC to ensure that in implementing the regulations it does in fact focus on meaningful and important problems for human health and the environment; exactly where the line must be drawn will have to wait for another day.

Applegate supports the principles set forth for establishing an alternatives analysis threshold as scientifically understood in that they deploy frequently used terms and concepts in a rational way, and establish a logical overall structure that can consider a wide variety of practical as well as human health and environmental concerns. CHANGE agrees with this and continues to support the establishment of each AAT on a case by case basis rather than use of a default de minimis exemption.

Applegate finds that the use of the term "adverse impacts" by the regulations is comprehensive and will ensure that AA's consider essentially any human health or environmental impact that might be of concern, and is therefore adequate to protect public health and the environment. Dr.

Applegate does take issue with the lack of an explicit standard for a responsible entity to choose or reject an alternative. This issue has been considered at length during the development of the regulations, and has been particularly problematic since no requirement for choosing a safer alternative exists in the enabling statute. CHANGE believes that the approach DTSC has taken to this issue in the regulations (that of requiring an AA, allowing a responsible entity to make its own decision without imposing a standard for the decision, then selecting a regulatory response based on that decision), complies with the intent and express language of AB 1879, and also accommodates the uncertainties currently inherent in using the still-developing alternatives assessment methodology.

Applegate makes his most important observations about the regulations under the heading "Big Picture Questions." There he notes that overall the regulations address the three "gaps," contain numerous mechanisms to promote regulatory efficiency, employ lessons learned from various chemicals regulatory programs around the world, and are clearly based on sound scientific knowledge, methods and practices. CHANGE agrees with all this. Applegate also notes several deficiencies (lack of mandatory data gathering mechanisms, lack of resources to implement the law) that CHANGE recognizes as well. But most importantly, Dr. Applegate concludes that the overall structure of the regulations is not designed as an elaborate and prescriptive system of regulatory controls, but rather as an efficient effort to promote a "culture of iteration and continuous improvement" that will allow manufacturers and regulators to examine products thoroughly, discover areas where innovation might yield benefits and then replace a chemicals when it becomes feasible. CHANGE agrees with this view of the overall intent and hope of the regulations and urges DTSC to continue refining their structure with these goals in mind.

#### Re Deborah Bennett

Dr. Bennett supports DTSC's proposal to use a "list of lists" to create a chemicals of concern list, calling it "efficient and effective." She recommends including emerging chemicals where there is potentially significant exposure, or persistence in indoor or outdoor environments, even if there may be limited toxicological data. This is a precautionary approach supported by common sense.

CHANGE encourages DTSC to incorporate Dr. Bennett's recommendation to give more weight to indoor environmental modeling as she notes that most consumer products are often used only in an indoor environment.

Dr. Bennett also points out that cumulative exposure is an important prioritization criterion. CHANGE agrees since cumulative exposure is a fact in the world backed up by scientific measurements.

### Re Norman Christensen

Norman Christensen supports the list of lists proposal as science-based and in line with the requirements of AB 1879. “The DTSC’s criteria for defining Chemicals of Concern is straight forward, thorough, and scientifically sound. Each of the criteria is based on solid peer-reviewed science. We can be confident that these criteria are sufficient to produce an initial Chemicals of Concern list. Similarly the process for making additions to the Chemicals of Concern list is clear and science-based.” Christensen also supports DTSC’s consideration of chemical and physical properties, volume in commerce, impacts on sensitive populations, exposure potential, and environmental impacts.

Christensen mentions of existing data gaps (a problem which this regulation is intended in part to address) when he says that “for the majority of chemicals, quantitative data exist for only a small subset of [DTSC’s] criteria and metrics.”

Christensen states that the product prioritization criteria and process DTSC has laid out are “logical and scientifically sound.”

Regarding AATs, which in the draft regulations are based on the individual chemical's hazard traits, Christensen believes the “principles underpinning the department’s Alternative Analysis Thresholds are clear and will ensure that approval of alternative chemicals is based on the best available science and technologies.”

### Re William Farland

William Farland says a large CoC list is scientifically defensible. He sees the proposed list as valuable and not redundant. “The use of chemical lists developed by “authoritative bodies” in California as well as elsewhere in the US and internationally is a scientifically defensible approach. Each of the lists was the product of a rigorous process for determining criteria for inclusion and all have undergone independent peer review at the process level if not at the individual listing step.”

Farland also supports a narrative process for chemical and product prioritization over a quantitative weighting scheme. He notes this is a sound decision given that available information will vary and there will be many differences from product to product that would be difficult to compare.

### Re George Gray

George Gray notes that a focus on life-cycle thinking is appropriate and can help avoid unintended consequences in choosing alternatives.

He also says the focus on all populations, including those that may be more vulnerable, is important and appropriate.

We note that Gray thinks a list of some 3,000 compounds will be too large, making it difficult to appropriately focus the effort. His concern is based in part on the "unevenness" of the database for many compounds; i.e., the data gap. He suggests weighting exposure more heavily in identifying CoCs. CHANGE would respond that while exposure will be considered by DTSC at the prioritization stage, the intent of the legislation is to focus on hazard traits when developing the CoC list. Relying too much on exposure at that stage runs counter to the language of the statute.

Gray praises DTSC for including aggregate and/or cumulative effects as a "worthy goal" while recognizing the difficulty in rigorously addressing them. CHANGE has consistently supported DTSC's efforts to build in cumulative exposure. We believe it is an important aspect of the program to retain and further develop since cumulative and ongoing exposure to multiple chemicals reflects the reality of today's chemical landscape.

Regarding alternative analyses, Gray says a flexible approach is necessary and appropriate. Requiring assessments of alternatives in a regulatory framework is one of the statute's most ground-breaking components. He realizes there will inevitably be much experimentation and learning early on, and that "too prescriptive an approach will stifle innovation and the ability to adjust to new scientific knowledge."

#### Re Dale Hattis

Dr. Hattis concludes that DTSC's proposal for developing the CoC list is "reasonably assembled" and a "sensible starting point." He stresses that DTSC "does not need to reinvent the wheel" in developing that list.

Hattis cites his own research about exposure to indoor air contaminants, suggesting that DTSC consider indoor air pollutants more carefully than outdoor ones. He mentions this specifically in the context of determining AAT exemptions. To the degree that AAT levels are set to be more protective, as Hattis seems to be proposing, CHANGE is in agreement.

Hattis anticipates that responsible entities will take steps to evade AAT levels by simply diluting the chemical of concern in consumer products (or as others have noted, by substituting a chemical for which little is known and therefore does not appear on the CoC list). Hattis supports DTSC's intention to rely on QSAR analysis to minimize regrettable substitutions, calling the use of structure-activity models as "very welcome."

He also notes that DTSC must be clear that non-chemical alternatives (such as "technology substitution") are fully acceptable options as alternatives. Ashford makes a similar comment.

Importantly from CHANGE's point of view, Hattis states it is "very important" for DTSC to include a petition process to "leverage the resources that environmental groups and other non-governmental organizations may make available to help implement the goals of the legislation."

Another important suggestion from Hattis pertains to regulatory responses. As written, the most extreme sanction contemplated is the prohibition of continued sales in California. Hattis appropriately calls for the addition of a recall of products already in the marketplace if there is an "imminent hazard." In its written comments to DTSC, CHANGE has made the same point in its written comments. If sales of a dangerous consumer product are prohibited without a mandatory recall mechanism, the likely outcome is the dumping of the products in dollar stores or other outlets patronized by lower income Californians.

Like CHANGE, Hattis strongly supports the requirement that Professional Ethics be a mandated requirement in Alternative Analysis assessors' certification.

#### Re Paul Locke

Overall, Paul Locke concludes that the regulations are based on sound science and practices.

Locke supports DTSC's proposed method for identifying CoCs, saying the approach "is appropriate for the purposes of this regulation. Each of these lists has been peer reviewed in some manner by the authoritative organizations that prepared them...and the process DTSC lays out for developing the CoC list] is science based and reasonable."

Locke says he assumes DTSC will confirm that each identified CoC is in fact tied to a hazard trait. From CHANGE's point of view, this is unnecessary. The proposed list of lists already identifies chemicals with hazard traits of concern – this is the reason they are on the various source lists.

With regard to product prioritization criteria, Locke states specifically that the descriptive, narrative methodology for classifying priority products "is science-based and makes sense given the nature of the statute and its intent." At the same time, he recommends "the addition of provisions that expand the information that is available to make these determinations." He suggests that the consistent reference to "available information" (which he assumes means "publically accessible") is limited and that a data call-in provision added to this section of the regulations would be appropriate - "To enhance the scientific bases of the decision-making described in this section, it would be useful to seek data from the public and members of the business community." CHANGE has long held that DTSC should exert its authority to require

data be generated and provided to the Department in order to ensure that chemicals in products are not exempted from the regulatory process because of a lack of data. We consequently agree with Professor Locke that a data call-in provision should be added to the regulations.

Locke recommends that Section 69503.2(a)(1)(B), which focuses on exposure scenarios, should go beyond consideration of “reasonable product use”. While reasonable product use is “an important starting point, it is also appropriate and scientifically necessary to include accidents and over-exposures, even if these resulted from unintended or improper use of the products. From a scientific perspective, it is essential to construct an exposure distribution, and understanding the ‘tail’ of this distribution (i.e., overexposed persons) has scientific value in exposure assessment and analysis. Such information should be available from federal or state agencies, or the companies themselves.” CHANGE agrees, especially in terms of the potential effects that accidents or improper use will have on workers and fenceline communities.

Regarding AATs, Locke does not support setting the default threshold for CoCs at the detectable minimum concentration by available analytical methods. This approach would be “counterproductive and actually defeat the incorporation of the best science.”

Locke takes the opportunity to suggest a redrafting of the definition of “sensitive subpopulations” to reflect scientific concepts. In particular, “pregnant women” should be replaced with women of “childbearing age” since a woman’s health before and after conception is key to a healthy pregnancy. CHANGE has explicitly made this comment on the draft regulations as well. Locke also wants to include environmental justice communities that are “differentially susceptible, or differentially exposed to CoCs, or more likely to be exposed to CoCs because they are bigger users of certain Priority Products.” CHANGE supports this recommendation.

### Re Ortwin Renn

Ortwin Renn's summary comment is that the "scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices."

Renn supports the large CoC list, calling it "complete" with the caveat that the addition of new chemicals should be done if new data becomes available or lists used are "augmented." Certainly, CHANGE agrees with him and other peer reviewers that keeping the CoC list as up-to-date as possible is the best scientific strategy.

### Jennifer Sass

Dr. Sass is yet another reviewer who supports DTSC's reliance on the science already assessed by authoritative bodies, leading to the current DTSC proposal for identifying chemicals of

concern. She goes further to suggest that DTSC should consider including all IRIS chemicals, and not just those based on neurotoxic endpoints -- as well as IARC 2A and 2B chemicals. CHANGE agrees since the intent of the enabling statute is to identify chemicals of concern based on hazard traits.

Sass also has noted the importance of having a process in place to update the CoC list. Since there are many examples of chemicals that have become of concern in the relatively recent past, it is essential that DTSC track the emerging science and keep its CoC list updated. Sass says the value of CoC list's "is in providing current information to the public about contaminants in consumer products."

Similarly, Sass supports DTSC's product prioritization criteria. Considering a wide range of factors will enable DTSC to base prioritization decisions on relevant scientific research and evidence.

Regarding AATs, CHANGE agrees with her that DTSC's plan to determine an AAT on a case-by-case basis is "scientifically understood, robust, and comprehensive," and will enable DTSC "to develop scientifically-defensible AATs for chemicals of concern."

Sass also says DTSC should be able to consider a range of "critical properties like inherent potency, the ability to bioaccumulate, the unintended presence in body tissues, and the disproportionate impact on sensitive populations or habitats. These critical properties provide guide posts for meaningful assessments of the impacts of chemicals, even when little is known of their toxicity." DTSC would be wise to build in these variables so it can act in a precautionary manner in the absence of complete information. She notes this should also extend to nanomaterials, a group of materials that CHANGE has advocated be explicitly covered by this regulation.

###



Representing Household & Institutional Products

Aerosol - Air Care - Cleaners - Polishes  
Automotive Care - Antimicrobial - Pest Management

January 4, 2013

Via E-Mail [GCRegs@dtsc.ca.gov](mailto:GCRegs@dtsc.ca.gov)

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

**Re: External Scientific Peer Review Reports for the Scientific Basis of the Regulations for Safer Consumer Products (R-2011-02)**

Dear Ms. Von Burg:

The Consumer Specialty Products Association (CSPA)<sup>1</sup> appreciates the opportunity to review and provide comments on the External Scientific Peer Review Reports for the Scientific Basis of the Safer Consumer Products Regulation. CSPA and our member companies have been actively engaged in the advancement 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 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 work with the Department and other stakeholders in the state to help spur green chemical innovation and continue to ensure that products are safe.

We welcome this opportunity to review and comment upon the expert peer review of the scientific basis for the regulation. While not the subject of this comment period, we have noted

---

<sup>1</sup> 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<sup>®</sup>, 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.

in previously submitted comments, 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.

There are a number of concerns we raise with the external scientific peer review, including:

- Improper external peer review process;
- Inadequate guidance by DTSC to the external peer reviewers for appropriate consideration of the “scientific basis” and “scientific portions” of regulation per California Health & Safety Code Section 57004;
- Incomplete disposition by DTSC of the external scientific peer reviewer comments per requirements of California Health & Safety Code Section 57004;
- Appearance of bias or conflict of interest.

We also call attention to a contravention of Administrative Procedures Act requirements: The Department sent a request for peer review on July 18, 2012 and the review was requested to be completed by August 30, 2012. Rather than wait to be informed by this peer review required by statute, DTSC proposed its draft regulations on July 27, 2012. The public did not have an opportunity to review the external scientific peer review comments, intended as an evaluation of the scientific basis of the regulation, during the public comment period on the draft regulation that ended on October 11. Rather, DTSC made the external scientific peer review documents available for public comment after the close of the public comment period on the regulation, in fact making it available at the end of 2012, when there are only three working weeks, which effectively precludes stakeholder scientists from properly evaluating the scientific knowledge, methods and practices supporting the regulations and the external peer review. Finally, as part of the rulemaking process, DTSC is required to accept any or all portions of the findings of the scientific peer review or explain any aspect of which there is disagreement with the findings of the scientific peer review. To date this action has not occurred. As such, our comments identify numerous scientific issues raised by the peer review that require action prior to adoption of the rule.

With respect to the selected peer reviewers, the process by which they were selected shows a decided lack of transparency and consequently calls into question the outcome and the intent of the subsequent reports. We think it is critical that the process be open and transparent to ensure that all stakeholders have confidence in the outcome of the peer review. First and foremost, it is vital that the reviewers have sufficient *and* appropriate expertise so that they can credibly comment upon the range of charge questions. For example, as noted in Mr. Ortwin Renn’s comments, “I am trained as a social scientist and worked in the fields of risk governance, technology assessment and public participation in science-based conflicts. Given this expertise I cannot comment on the natural science aspects of the questions posed to me,” thus effectively removing himself from considering the majority of the charge questions. This is not to say that

the peer review board is not eminently qualified but rather that their experiences appear to sometimes be inappropriate for their task.

Secondly, there appears to be a significant flaw in the selection process of the peer review board. A March 29, 2012 letter from the California Water Boards indicated that the University of California had identified six peer reviewers, Drs. Bennett, Farland, Gray, Hattis, Renn and Sass<sup>2</sup>. However the final list of peer reviewer included four additional individuals (Drs. Ashford, Applegate, Christensen and Locke). How and when were these individuals added? This does not be consistent with the External Peer Review Process and appears to show a lack of transparency.

Thirdly, it is critical that the reviewers are unbiased and that obvious conflicts are disclosed or appropriately counter-balanced by other peer reviewers. As noted in the DTSC Transmittal Memo:

Each candidate who was both interested and available for the review period was asked to complete a Conflict of Interest Disclosure form and send it to me for review. In follow-up communications with selected candidates, I asked for certain clarifications and affirmation there is nothing in their background: a) that might be reasonably construed by others as affecting their judgment, and b) which might constitute an actual or potential source of bias. They also were asked to affirm they would be able to perform an objective and independent review.<sup>3</sup>

We appreciate the reviewers were selected by the University of California on behalf of DTSC, however, we think there is an obvious appearance of bias in that at least one of the reviewers: One reviewer is employed by a prominent non-profit organization which has taken a strong stance on aspects of the regulation development<sup>4</sup>, yet due to a dual appointment was afforded to opportunity to be a peer reviewer. In particular, it is disingenuous that members of the peer review are initially characterized as university faculty (at least on the DTSC website) when their opinions may be influenced by their other employment.<sup>5</sup>

A significant number of scientists employed by our member companies hold appointments at prominent universities. As is appropriate, we do not use our university affiliations when making public comments on behalf of our employers. In addition, the “tone” of several reviewers’ comments call into question their impartiality and could reasonably be construed as biased judgment, giving an impression that they are “promoters” of the approach rather than making an assessment of whether (or not) the regulatory provision being discussed is consistent with generally accepted practices. Correspondingly, the reviewers were over-representative of academia and had little to no practical industrial experience. Again, this tends to prejudice the comments toward a tone lacking sensitivity to economic and market pressures that could inform the regulations and make them more practical to “real world” criteria. In other words, there was

---

<sup>2</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Transmittal-Memo.pdf>

<sup>3</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/upload/Transmittal-Memo.pdf>

<sup>4</sup> For example, [http://switchboard.nrdc.org/blogs/jsass/we\\_wont\\_prevent\\_cancer\\_until\\_w.html](http://switchboard.nrdc.org/blogs/jsass/we_wont_prevent_cancer_until_w.html) or [http://switchboard.nrdc.org/blogs/sjanssen/the\\_governors\\_holiday\\_gift\\_to.html](http://switchboard.nrdc.org/blogs/sjanssen/the_governors_holiday_gift_to.html)

<sup>5</sup> The university affiliation was ascribed to the peer reviewers when the peer reviewer comments were initially posted. The affiliation information was removed from the website at some point afterwards.

a certain naiveté reflected across the reviewers' comments reflecting their academic orientation. Consequently the reviewers generally ignored that many different agencies (international, national, state/provincial, and local) rigorously review chemicals in commerce before entrance into the channels of trade. It should also be pointed out that the membership of the Green Ribbon Science Panel attempted a balanced representation by including academia, industry and NGO concerns, and that the lack of similar attempts to balance the peer review representation is a significant shortcoming.

To that end, it is important to consider the charge questions given to the peer reviewers to see how the questions compare to the scientific concerns raised in our previous comments and by the Green Ribbon Science Panel. It is critical to note that the actual charge questions provided to the peer reviewers were not contemporaneously released publically nor was any public input garnered or submitted to aid in the charge question development. While the external peer review instructions detail the materials provided to the reviewers, there appears to have been confusion that all materials were provided. For example, reviewer Gray noted that he was "unable to locate Chapter 54 with more detailed descriptions" (OEHHA's previously adopted Hazard Traits regulation) which seems a critical oversight when considering the charge question of "adverse" impacts or as reviewer Renn noted "it might be in some other sections that were not sent to me."

One particularly contentious issue for our association is the "Alternatives Analysis Threshold" and it is troubling that only two of the reviewers (Bennett and Locke) even recognized the significant analytical challenges associated with this area. It was disheartening to see little support for or even recognition of the use of international *de minimus* standards, at least as a starting point for the development of a new regulatory environment. As noted by reviewers Applegate, Bennett, Farland and Gray, the default Alternatives Analysis Threshold is driven more by policy and administrative decisions rather than a broad scientific foundation; thereby moving farther away from a "scientifically-valid" approach that enjoys broad general support.

Several reviewers made the valid observation that the "list of lists" approach is only as useful as the most recent updates, implying that the regulations might be deficient if the contemporaneous nature of the documents was lost over time. This concern noted by the reviewers echoes our concern that a scientifically valid process be established for both establishment and continued review of the list to obviate concerns with politicization and non-scientific manipulation of the list.<sup>6</sup>

In addition, the reviewers were asked to comment broadly upon the scientific aspects of the regulation and generally the reviewers took this charge very seriously and provided meaningful comment. However it should be noted that a number of the reviewers expressed opinions not necessarily supported by existing scientific understanding or consensus.

Below are specific comments and concerns raised by the peer reviewers we think are worthy of additional response or other consideration by DTSC as part of the peer review process.

---

<sup>6</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Combined-SCP-Comments.pdf>, CSPA Comments, § 69502.2 Chemicals of Concern Identification, page 511.

**Applegate peer review comments:**

- Reviewer acknowledged lack of scientific expertise and focused on non-scientific issues. “As a non-scientist, I will focus on their coherence as regulations of toxic chemicals.”<sup>7</sup>
- Reviewer’s concluded that:  
In sum, the principles for the threshold exemption are “scientifically understood” in that they deploy frequently used terms and concepts in a rational way. The use of the terms (and) concepts is also logical in the context of the overall structure of the threshold exemption provision, described above.<sup>8</sup>

We do not believe this addresses Charge Question 3.

- Reviewer noted that the Safer Consumer Products Regulation is meant to address “the use of untested chemicals in consumer products.” If what the reviewer is saying is true, then, conversely, if a chemical has been subject to testing, does it not argue that it should be *eliminated* from consideration under the Safer Consumer Products Regulation? We disagree with the reviewer’s contention that chemicals in consumer products are untested.
- Reviewer noted significant concern with listing process in that :  
What is missing in § 69503(b), as elsewhere in the CCSPAR (SCJ), is a statement of a clear standard for placement on the list or not. The regulations come closest to a precise in the threshold (exemption) procedure (§ 69503.6), but the overall regulatory strategy is to emphasize casting a wide net, multi-step processes, exhaustive enumeration of relevant factors, and professional judgment.

Although the reviewer’s concern is not fully clear, we believe that this concern needs to be addressed.

- Unclear how reviewer concluded that “the process for establishing the alternatives analysis threshold exemptions (formerly the *de minimis* exemption) serves to focus regulatory and compliance efforts on chemicals and products that are most likely actually to pose a risk based on either the amount of hazardous material or the degree of exposure”.<sup>9</sup> Given the breadth and potential scope of the Chemicals of Concern, it would seem to argue to the contrary. In addition, details of this process have not been published and making a scientific judgment does not seem possible.
- Reviewer’s contention that “The carefully structured approach of listing, priority setting, and detailed alternatives analysis gives manufacturers both the opportunity and incentive to revise products without resource-intensive regulatory action,” is an opinion and does not have any established scientific basis.

---

<sup>7</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/5-Applegate.pdf>, page 4 with respect to Alternatives Analysis Threshold Principles.

<sup>8</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/5-Applegate.pdf>, page 5 with respect to Alternatives Analysis Threshold Principles.

<sup>9</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/5-Applegate.pdf>, page 9.

- Reviewer's assumption of collaboration between the regulated and the regulator strikes one as being naïve; especially since there is no "safe harbor" provision for the regulated entities that cooperate.
- Reviewer's contention that "This surely demonstrates that the Precautionary Principle – often unjustly derided as anti-scientific – can indeed co-exist with sound science," is an opinion and does not have any established scientific basis.<sup>10</sup>

#### **Ashford peer review comments:**

- Reviewer asserts that "in general, the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices," it is unclear what specific scientific knowledge, methods or practices that this assertion relies upon.
- Reviewer raises the point that "the substitution criteria should not be restricted to chemical substitutes," and recommends "safer technological or administrative approach that delivers a comparable, but safer functional purpose". We believe the regulation provides the regulated entity the discretion to consider any option the Alternatives Analysis process.
- Reviewer's contention that "Europe and Asia are advancing in chemical innovation, and the chemical industry in the United States cannot afford to lag behind in the development and deployment of environmentally safer chemicals and processes,"<sup>11</sup> is an opinion and does not have any established factual basis. While the regulatory influences of the European Union and REACH are clear, one could argue that a less stringent regulatory framework in parts of Asia has led to the unsafe products in the California marketplace<sup>12</sup>.

#### **Bennett peer review comments:**

- Reviewer's comments appear to be driven more by policy considerations rather than scientific ones.
- Reviewer's assertion that:  
It is important to also include emerging chemicals for which there might be significant exposure due to their used in consumer products or their persistence in either the indoor or outdoor environments, but for which there may be limited toxicological data.

We do not believe this assertion is supported by scientific and/or other relevant data.

- Reviewer raised a scientific issue noting a lack of clarity between the ISOR and regulation with respect to evaluation of structurally similar compounds. We agree and recommend that the text of ISOR/regulation be clarified accordingly.
- Reviewer recommended the inclusion of indoor environmental modeling to better describe exposure of numerous consumer products. We believe this is appropriate tool to consider during the exposure assessment process.

---

<sup>10</sup> For example, see Foster, K. R., Vecchia, P., and Repacholi, M. H. *Science* 12 May 2000: 288 (5468), 979-981.

<sup>11</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/6-Ashford-combo.pdf>, page 5.

<sup>12</sup> For example, DTSC's site on "Lead In Jewelry", <http://www.dtsc.ca.gov/leadinjewelry.cfm>

- Reviewer raised a scientific issue noting that the regulation “should explicitly consider and note direct consumer exposure from the product.”<sup>13</sup> We believe a more explicit consideration would likely improve the prioritization setting process.
- Reviewer raised a scientific issue noting that the regulation does not clearly define “products” and needs improved guidance. This area of ambiguity has been raised in CSPA’s previous comments<sup>14</sup>.
- Reviewer raised an interesting assessment around the breadth of the Safer Consumer Products Regulation outside of California, in that California cannot regulate outside its jurisdiction.
- Reviewer raised an issue that the manufacturing location apparently not considered in the regulation. We agree this raises a number of concerns about manufacturing practices and life cycle considerations that merits additional clarification within the ISOR or regulation.
- Reviewer raised a significant scientific issue that “chemical with multiple routes of exposure would result in higher priority over a product with a single route of exposure.” The reviewer correctly notes that the magnitude of exposure is much more important consideration than the number of exposure pathways and recommends modification of the regulation.
- Reviewer raised a significant scientific issue that “§69503.5(c)(3) is either not clearly written or may result in thresholds that are not reasonable” We agree with the reviewer’s recommendation for additional guidance to clarify how threshold levels will be balanced with technical difficulties.
- Reviewer raised a scientific issue that traditional life cycle assessments do not adequately address all factors that are critical to quantifying all public health impacts. We concur that any factor should be considered during the Alternatives Analysis that has a significant public health impact.<sup>15</sup>
- Reviewer raised a scientific issue and inconsistency in that:
  - the regulations establish a process for evaluating chemical concerns in consumer products, and their potential alternatives, to determine how to best limit exposure or to reduce the level of hazard posed by chemical of concern’ which seems to imply a focus on hazard reduction, while the A-M list for the life cycle impact assessment encompasses a much broader range of endpoints.

We are unclear of the reviewer’s concern but support strategies that reduce exposure or hazard.

- Reviewer raised a valid concern that the greatest vulnerability to consumers is often “off-brand” items and that the current regulation does not address this concern.

---

<sup>13</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/7-Bennett.pdf>, extended discussion page 2&3.

<sup>14</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Combined-SCP-Comments.pdf>, CSPA Comments, § 69503 General, page 531.

<sup>15</sup> See example, McKone *et al*, “Integrating Human Indoor Air Pollutant Exposure within Life Cycle Impact Assessment”, *Env. Sci. Tech.*, 2009, **43**, 1670-1679. (<http://pubs.acs.org/doi/pdf/10.1021/es8018176>)

### **Christensen peer review comments:**

- Reviewer noted involvement in the evaluation in an earlier stage of the proposed regulation. It is unclear if this involvement is consistent with External Peer Review Guidelines in that “No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule.”
- Reviewer contention that “The emphasis on ‘detection’ as a minimum threshold rather than ‘quantitation’ is consistent with our understanding that chemicals may have adverse impacts on health or ecosystems at concentrations below levels of quantitative measurement,” is an opinion and does not reflect an established scientific consensus<sup>16</sup>.

### **Farland peer review comments:**

- Reviewer appropriately noted that DTSC’s need to address how it will deal with a decision to differ in its determination around potential hazard compared to the original source list and that the paradigm around identifying hazards is changing, although business and academia may not agree on the results of those changes.
- Reviewer correctly noted that the (in)frequency and validity of updates to the underlying referenced lists may impact the implementation.
- Reviewer raised the valid scientific issue of “The inherent potency of the Chemical of Concern” and the need discussion of available test data and an evaluation of the statistical treatment of the toxicological data<sup>17</sup>.
- Reviewer appropriately raised the scientific issue that “The presence or absence of a threshold dose response is rather simplistic” and recommended that this area be bolstered by inclusion of more rigorous discussion of dose response and thresholds<sup>18</sup>.
- Reviewer raised the scientific issue that “the Cumulative exposures of other Chemicals of Concern that exhibit the same hazard trait leaves much of the scientific complexity unstated.” We believe that the suggestion that exposures exhibiting the same hazard are cumulative vastly oversimplifies modes of action and toxicological endpoints<sup>19</sup>.
- Reviewer correctly noted that the default Alternatives Analysis Threshold value of the limit of detection is a policy-based decision rather than a science-based decision.

### **Gray peer review comments:**

- Reviewer succinctly states the challenges associated with “doing alternatives assessment right” and the choices involved. It bears repeating two points noted in the reviewer’s comments.

---

<sup>16</sup> For example, see Kamrin, Michael, “The “Low Dose” Hypothesis: Validity and Implications for Human Risk”, *Int. J. Toxicology*, 2007, **26**, vol. 1, 13-23 or Rhomberg, Lorenz R., and Julie E. Goodman. “Low-Dose Effects And Nonmonotonic Dose-Responses Of Endocrine Disrupting Chemicals: Has The Case Been Made?” *Regulatory Toxicology and Pharmacology*, **2012**, 64 (1): 130-133. <http://dx.doi.org/10.1016/j.yrtph.2012.06.015>

<sup>17</sup> See National Research Council (2009) *Science and Decisions: Advancing Risk Assessment*. National Academies Press, Washington, D.C. [http://www.nap.edu/catalog.php?record\\_id=12209](http://www.nap.edu/catalog.php?record_id=12209)

<sup>18</sup> Ibid.

<sup>19</sup> Ibid.

- “First, our traditional approach to chemical assessment can easily confuse and mislead the effort.”
- “Second, even if we could appropriately assess the risks of alternative chemicals well, choosing between alternatives means weighing incommensurate outcomes.”<sup>20</sup>
- Reviewer’s example of carbon tetrachloride is illustrative of the scientific complexities involved with assessing chemical risk and that different scientific experts can look at similar data and reach differing conclusions.
- Reviewer’s comment “Alternatives assessment must be transparent about how different attributes are considered and weighed against each other. The use of tools like multi-criteria decision theory can advance the credibility of these decisions.” is an important insight.
- Reviewer raised the appropriate scientific issue that the Chemicals of Concern list will be too large and that the prioritization criteria are too broad to improve the specificity of the list.
- Reviewer expressed significant concern with the over-reliance on specific hazard traits for identification and *de minimus* determinations due to differences in dose response and unevenness in toxicology databases. We agree with his recommendation is to utilize potency and levels of human or environmental exposure as better means of prioritizing the Chemicals of Concern list.
- Reviewer raises the valid concern that a data-rich chemical could be replaced by a data-poor chemical inviting the possibility of regrettable substitutions.
- Reviewer repeatedly raised the significant scientific issue that reliance on biomonitoring lists is an inefficient means of prioritizing the Chemicals of Concern list.
- Reviewer expressed concern with “how ‘Reliable information concerning...exposure to the Chemical(s) of Concern...’ can be used to set priorities.” Distinguishing between natural and disparate sources of the Chemicals of Concern’s potentially found in consumer products is fraught with significant complexities<sup>21</sup>. We believe this would also seem to argue for maintaining the *de minimus* threshold approach to refine efforts appropriately to the area of greatest hazard or those known with the greatest confidence.
- Reviewer correctly recognized the importance of public health or environmental risk reduction as an important prioritization factor but expressed concern about the lack of specificity about *how* hazard and exposure will be considered.
- Reviewer appropriately noted that “the Alternatives Analysis Threshold exemption is an important administrative tool for focusing effort and resources,” while noting a significant number of scientific and technical issues requiring “more specificity to ensure consistency and fairness in their application.”
- Reviewer correctly noted the distinction that “adverse effects” are actual outcomes and that an impact without an outcome is by definition not “adverse.”

---

<sup>20</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/10-Gray.pdf>, page 1.

<sup>21</sup> See reference noted by reviewer or OEHHA’s Interpretive Guideline No. 2012-01, “Consumption of Methanol Resulting from Pectin that Occurs Naturally in Fruits and Vegetables”, [http://www.oehha.org/prop65/ig/pdf/IG\\_12001Methanol.pdf](http://www.oehha.org/prop65/ig/pdf/IG_12001Methanol.pdf)

- Reviewer astutely noted that “flexibility allowed in the conduct of Alternatives Analysis is appropriate and necessary,” and that an overly prescriptive approach will stifle innovation.
- Reviewer raised the valid concern about the lack of specificity and vagueness of “how one would determine that an ‘alternative chemical poses equal or greater adverse public health and/or environmental impacts than the Chemical of Concern.’”
- Reviewer correctly raised concern about the lack of specificity and transparency of “the need for weighing various attributes of alternative chemicals” and the lack of guidance describing this process.

#### **Hattis peer review comments:**

- Reviewer noted that the initial list of Chemicals of Concern approach “is a quite sensible starting point, as it makes use of extensive work done by previous expert evaluators,”<sup>22</sup> We believe that this is an opinion and that it is important to establish appropriate criteria for inclusion on the Chemicals of Concern list.
- Reviewer cites an unsubstantiated calculation as a basis for revamping the prioritization process described in the regulation.<sup>23</sup> The reviewer goes further and notes that it is “difficult to assess a chemical without making implicit or explicit assumptions related to use types,” which is the process the reviewer described in their earlier unsubstantiated calculation. It is unclear to us what scientific point the reviewer is attempting to make in this response.
- Reviewer correctly notes a scientific concern that the “narrative” approach alludes to a weighing of differing toxicological and/or ecological effects without specifying the priority of the various effects.
- Reviewer notes the valid scientific concern that there is a “need for consistency across chemicals and chemical uses in the uncertainty metric that will be used for priority ranking” and recommends more detailed guidance.
- Reviewer notes a scientific concern that “it would be helpful to add one or two considerations relevant to the expected ‘intake fraction’”<sup>24</sup> and goes into further detail about the inherent difficulty of comparing differing use patterns of differing products. The concerns expressed by the reviewer would be obviated by proper (and the importance thereof) selection of a product to ensure similar use patterns. We think it is unclear if the reviewer was aware of the product category provision of the regulation.
- Reviewer notes a concern with responsible entities whom “qualify for exemption by simply marketing their product in a more dilute form” as a means to bypass scrutiny. While this may be a concern of the reviewer, we do not believe this has any real world relevance. Products need to work and there are significant benefits to providing products in concentrated forms into the marketplace. For example, providing a concentrated detergent product that is diluted with water upon usage imparts a significant reduction in transportation costs and greenhouse gas emissions.

---

<sup>22</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/11-Hattis.pdf>, page 3.

<sup>23</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/11-Hattis.pdf>, page 5.

<sup>24</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/11-Hattis.pdf>, page 7.

- Reviewer correctly notes a concern that the ISOR “provides no analysis of the expected cost or benefit of the regulations pending identification of priority product categories.” This highlights the importance of completion of an economic analysis which was noted in CSPA’s previous comments.<sup>25</sup>

**Locke peer review comments:**

- Reviewer expressed comfort with assumption that DTSC would review “list of lists” to confirm the presence of a hazard trait, etc. and, therefore, no need for additional regulatory guidelines for classifying Chemicals of Concern. We believe that it should be noted that this approach would be counter to other chemical regulatory schemes that clearly articulate the criteria by which a material/constituent qualifies for inclusion on a “list”.<sup>26</sup> The lack of details of the process for determination of the “list of lists” continues to be a significant concern with the proposed regulation.<sup>27</sup>
- Reviewer noted that “descriptive narrative approach is science-based and makes sense given the nature of the statute and its intent” while expressing an option to “seek data from the public and members of the business community” possibly via data call-in process. We would note that if a “data call-in” provision were included in §65903.2 to enhance decision-making, it raises a concern as to both how the information is “vetted”, especially when received from a source that has not been peer-reviewed and by what means company-generated data will be kept confidential. Conversely, a data call-in suggests that additional information may allow mitigation rather than elimination of Chemical of Concern in its entirety.
- Reviewer correctly notes that the Alternatives Analysis Threshold Level should be determined from public health and/or environmental health level rather than the detection limit of the chemical.
- Reviewer notes that combinations of chemicals can have both additive and/or multiplicative effects and that this should be accounted for in Alternatives Analysis Threshold Level determination. We believe that it should be noted that this is an oversimplification of the role of additive, synergistic and antagonistic toxicological effects which can depend upon chemical/physical characteristics and/or biological interactions of chemicals.
- Reviewer correctly notes that the term “women of childbearing age” is a more accurate descriptor than “pregnant women”.

---

<sup>25</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Combined-SCP-Comments.pdf>, CSPA Comments, “Inadequate Economic Analysis”, page 522.

<sup>26</sup> For example, Washington has a much more detailed process for identifying Chemicals of High Concern list (<http://www.ecy.wa.gov/programs/swfa/cspa/pdf/CHCCrationale.pdf>) or Minnesota’s Chemicals of High Concern List Methodology (<http://www.health.state.mn.us/divs/eh/hazardous/topics/toxfreekids/chclist/methodology.pdf>)

<sup>27</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Combined-SCP-Comments.pdf>, CSPA Comments, § 69502.2 Chemicals of Concern Identification, page 511.

**Renn peer review comments:**

- We believe the reviewer's comments are fairly balanced and recognize the complexity of chemical management.
- Reviewer correctly raises a concern over the number of criteria related to priority as well as the concern over redundancy between lists. The reviewer recommends a more systematic approach to the priority list.
- Reviewer appropriately notes that provisions seem to assume that there is a single threshold relevant for comparison purposes among alternative chemicals whether it relates to endpoints or priority of other desirable environmental outcomes.
- Reviewer correctly notes that all chemicals and/or chemical combinations have the ability to cause harm and that the dose should generally be taken into account and not merely its presence.
- Reviewer appropriately recommends improving the definition of "Adverse Impacts" to better clarify the term.

**Sass peer review comments:**

- Reviewer argues for a requirement for DTSC to update the Chemical of Concern list on a regular basis. We agree that this is a valid point provided it allows for removal of chemicals, as well as, the addition of chemicals as implied by reviewer.
- Reviewer recommends the addition of IRIS chemicals that include reference concentration (RfC) or reference dose (RfD) values for other toxicological endpoints. We believe it should be noted that within the Initial Statement of Reasons, DTSC identified the IRIS database as the primary source for neurotoxicity as "a hazard trait that has not been recognized in the other lists," and Group A, B1, or B2 carcinogens. While the IRIS database captures information on other endpoints, the toxicological emphasis has been elsewhere and the other indicated source lists would serve as more appropriate sources.
- Reviewer's comment "Waiting for chemicals to become Group 1 carcinogens means waiting for toe tags and death certificates, and California is correct to do better than that at preventing cancer"<sup>28</sup> shows a profound misunderstanding of the IARC process<sup>29</sup> and has no place in a rational, scientific discussion.
- Reviewer argues for expansion of the Safer Consumer Products Regulation to include chemicals listed under the SDWA, and other chemicals already captured under different regulatory programs. We believe this recommendation is currently prohibited from the statute due to existing regulatory schemes and expands the reach of the Safer Consumer Products Regulation beyond its original intent.

---

<sup>28</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/14-Sass.pdf>, page 2.

<sup>29</sup> <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>

### **Summary and Conclusions**

As noted in the peer reviewer comments, there are a significant number of scientific issues raised that have not adequately been addressed by the existing form of the regulation. It is clear that DTSC has not disposed of the external peer review in a manner consistent with External Scientific Peer Review Guidelines.

The board, department, or office may accept the findings of the external peer review entity, in whole, or in part, and may revise the scientific portions of the proposed rule accordingly. If the board, department, or office disagrees with any aspect of the findings of the external scientific peer review entity, it shall explain, and include as a part of the rulemaking record, its basis for arriving at such a determination in the adoption of the final rule, including reasons why it has determined that the scientific portions of the proposed rule are based on sound scientific knowledge, methods, and practices.<sup>30</sup>

This is abundantly clear by simply noting the reviewer's concerns with the "list of lists" approach some of which are diametrically opposed to one another. It is unclear, and appears unlikely, the scientific issues raised in our comments or in the peer review will be addressed prior to release of the next draft release (and were not addressed in the recently updated Initial Statement of Reasons) of the regulation.

We support the external peer review process and when conducted properly the reviewers' feedback strengthens the process. The reviewers undoubtedly expended great effort in the course of their review and, as of yet, it is unfortunate that their efforts have not been utilized in a practical and meaningful manner. Consequently, in order to fully utilize the external peer review process per California Health & Safety Code Section 57004, CSPA requests that DTSC:

- Address the numerous scientific issues identified within the external peer review comments;
- Address the numerous concerns we have expressed about the propriety of the external peer review process;
- Address the incomplete disposition by DTSC of the external scientific peer reviewer comments;
- Improve the inadequate guidance by DTSC to the external peer reviewers to ensure appropriate consideration of the "scientific basis" and "scientific portions" of regulation;
- Remove the appearance of bias or conflict of interest by members of the peer review board, and
- Request that DTSC empanel and complete an additional external peer review in the event of any "significant" revision to the regulation.

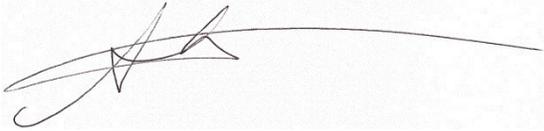
CSPA appreciates the opportunity to comment on the Safer Consumer Product Regulation External Peer Review and remains supportive of the principles of Green Chemistry and programs that are consistent with those principles. We appreciate the significant stakeholder outreach and

---

<sup>30</sup> California Environmental Protection Agency (Cal/EPA) External Scientific Peer Review Guidelines, <http://www.calepa.ca.gov/publications/Reports/PEERRVW.PDF>

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.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Steven Bennett', with a long horizontal line extending to the right.

Steven Bennett, Ph.D.  
Director, Scientific Affairs

A handwritten signature in black ink, appearing to read 'Kristin Power', written in a cursive style.

Kristin Power  
Director, State Affairs – West Region

cc: Matthew Rodriguez, Secretary, California Environmental Protection Agency  
Gina Solomon, Deputy Secretary for Science and Health,  
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



**EUROPEAN COMMISSION**  
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL  
Internal Market for the Free Movement of Goods  
Prevention of technical barriers

Brussels,  
LK/nv – entr.c.3(2012)1776743

---

**E-MAIL**

---

**To:** TBT Enquiry Point of the United States      **E-mail:** ncsci@nist.gov

**Copy**      Ms M P Nicora  
EU US Delegation

**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 + 1

---

**Subject:** **G/TBT/N/USA/727/Add.2 – DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS" – EU comments**

---

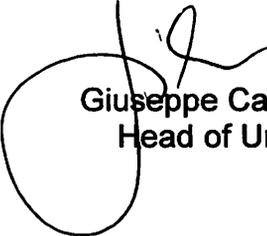
**Message:**

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 L. KOJNOK  
Telephone:(32-2) 295 09 08  
E-mail : [eu-tbt@ec.europa.eu](mailto: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 like to thank the US authorities for providing the information that the Department of Toxic Substances Control (DTSC) added ten external scientific peer review reports to the notified technical regulation providing for an additional commenting period until 30 December 2012.

While the EU has no specific comments on these reports, the EU would like to reiterate its general and specific comments issued on 11 September 2012 in relation to this notification.

To recall, with regard to the main principles of the draft Regulation, the EU is concerned about three issues:

- 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 3<sup>rd</sup> countries (Article 5.1.1 of the TBT Agreement).

For more details on these general comments and on the specific comments, the EU would refer to its comments of 11 September 2012.

The EU would like to inform the US authorities that prior to the adoption of the REACH legislation, the so-called Strategic Partnership on REACH Testing (SPORT), had helped to improve the draft legislation in terms of feasibility and proportionality considerations. The EU would recommend to the Californian DTSC to consider also conducting a feasibility analysis or 'beta-testing' with some pioneering companies before enacting the legislation, similar to that which was conducted in the EU.

As the EU has not yet received any reply from the US authorities, the EU looks forward to receiving a reply to comments that it has provided. The EU would appreciate the possibility to discuss these comments directly with the relevant authorities in California.

\*\*\*



December 21, 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](mailto:gcregs@dtsc.ca.gov)

**Re: Comments on External Scientific Peer Review Reports**

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 November 30, 2012 posting of External Scientific Peer Review reports on the July 2012 Safer Consumer Products formal draft rulemaking.

GMA has 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/>).

GMA has a number of serious concerns with the process employed in fielding and publishing the peer reviews. In addition, we are concerned with the content of a number of the reviews. These concerns are detailed in Attachment A.

GMA has been a strong advocate for critical scientific aspects within the regulations to maximize the potential for the Green Chemistry program to build a reputation as strong and science-based with meaningful improvements in public health and the environment in California. We have consistently advocated for a number of important scientific policies:

- Using a science-based approach that evaluates hazards and the potential for exposure in identifying a narrow set (100-200) Chemicals of Concern for the initial focus in the program and describing others as "Chemicals of Interest".
- Employing a quantitative approach to product prioritization that evaluates levels of hazard and exposure to identify high priorities, focusing initially on a narrow set of Priority Product (PP)/Chemical of Concern (CoC) pairs.

- Setting a “deminimis” or “AA Threshold Concentration” at a level consistent with protective scientific standards set elsewhere in federal and international chemical control systems and providing regulatory certainty.
- Explicitly allowing companies to provide a “safety case”, demonstrating that products are low risk based on how they are designed and used.
- Employing strong science-based approaches to Alternative Analysis that are routinely executed as part of industry's ongoing research and development and product improvement programs.
- Employing scientifically adequate definitions for “adverse impacts”, “reliable information” and “reliable information demonstrating the occurrence of exposure”; and
- Emphasizing the application of weight of evidence evaluation in department and regulated community decisions.

As has been the case since its inception, 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 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

## Attachment A

### Peer Review Process Concerns

**Reviewer Selection.** A March 29, 2012 letter from the California Water Boards indicated that the University of California had identified six peer reviewers, Drs. Farland, Gray, Renn, Hattis, Bennett and Sass, the first three of whom had been external reviewers of previous drafts of the regulation. Why and how did Drs. Ashford, Applegate, Christensen and Locke get added to the roster? What was the driver to make changes? DTSC has an obligation to follow California rules to ensure an unbiased Peer Reviewer selection process and to be transparent in doing so. From the information posted on DTSC's website, it's not clear that this is the case.

**Timing of Publication and Comment.** Per the July 18, 2012 Request Memo, peer reviewer comments were to be completed by August 30, 2012. Why did public release of these not happen until November 30, 2012? This is three months after receipt by the Department, seven weeks after the deadline for public comments on the SCP proposed regulation and presumably just a few days or weeks before the expected publication date of final regulations. To the extent that the Department is considering the Peer Review Reports in finalizing the regulations, it should delay their publication until after it considers public comment on the Reports.

**Questions for Peer Review.** The revised scope of work, dated 18 July 2012, requests a determination whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices. These are set out in Attachment 2: Scientific Factors – Peer Review Points.” In summary, a determination has been requested regarding:

1. The use of chemical lists used to produce the initial Chemicals of Concern (CoC) list [section 69502.2]
2. The use of initial and key product prioritization criteria to identify consumer products containing CoCs as potential and high Priority Products [section 69503.2]
3. The principles that will be used to develop the Alternative Analysis Threshold [section 69503.5], and
4. The definitions of various “adverse” impacts and general usage of the term “adverse” impacts enabling a determination that is adequately protective of public health and the environment.

In addition, DTSC asked reviewers to contemplate certain “big picture” questions, such as:

- Are there additional scientific issues that are part of the scientific basis of the proposed rule that are not covered?
- Taken as a whole, is the scientific portion of the rule grounded in sound scientific knowledge, methodology and practice?

GMA agrees that these are important scientific issues for review. However, there are a number of science issues that we and others have repeatedly raised that are critical to the scientific basis of the regulations. For instance successful alternative analysis demands in depth scientific rigor and the Department has proposed a number of science approaches in that section, yet it is not an explicit request for the peer reviewers. In addition, extensive argumentation has been provided to DTSC on scientific concerns related to the definition of “reliable information” and “reliable information demonstrating the occurrence of exposure” which, as reflected in the latest version of the draft rule, automatically define everything from a wide variety of sources as

*de facto* “reliable” regardless of the actual reliability of any specific studies. Finally, the absence of emphasis on weight of evidence and its application to decisions by the Department has also been identified as a major concern. Why have peer reviewers not been specifically consulted on these important and recurring scientific issues that have consistently been raised and reiterated by stakeholders?

### **Comments on Peer Review Report Content**

#### **Overarching Reviewer Comments:**

GMA has been a strong advocate for critical scientific aspects within the regulations to maximize the potential for the Green Chemistry program to build a reputation as strong and science-based that will make meaningful improvements in public health and the environment in California. Reviewers recognize this as well with Dr Gray recommending the establishment of “a system that truly leads to good choices that result in reduced risk” and Dr Farland indicating that “the Department should use the best available science and judgments in its decision-making.” We agree with Dr Applegate that DTSC “should be efficient, employ deliberative approaches, and use evidence-based methodologies.” While we agree with Dr Farland that DTSC should “embrace scientific advances”, we would caution that the Department should not be employing every new theory that arises, but rather should adopt advances as they become settled science. We disagree with Dr Ashford’s suggestion to expand the program scope to include industrial and agricultural workplaces—the statute provides no such authority. GMA has critiqued DTSC’s decision not to conduct an analysis of cost and benefit for the SCP regulation, a view that is shared by Dr Hattis, who calls the decision a “cop-out”. Finally, we disagree with Dr Hattis that there should be any recall of product already sold. First of all, this regulation is not about identifying unsafe products, but encouraging the production of ‘safer’ products and the statute does not provide recall authority. For truly unsafe products there are regulatory agencies covering all of the consumer product categories, which have the authority to take recall action in cases where that is appropriate.

#### **Reviewer Comments on Alternative Assessment (AA)**

GMA has advocated for employing strong science-based approaches to Alternative Analysis, noting that these are routinely executed as part of industry's ongoing research and development and product improvement programs. Dr Gray and Dr Bennett are correct in indicating the complex nature of AA’s and that the weighing of alternatives and making decisions are ultimately based on value judgments. While we agree with Dr Gray that AA’s must be transparent on how different attributes are considered and weighed against each other, the protection of confidential business information is not mentioned, which is an important issue in how much of that information would be disseminated to the public. Dr Bennett indicates that “standard life cycle assessment is not as well suited to comparing public health impacts as it is to environmental and sustainability factors”, and that has been the experience in industry. Nevertheless, human and environmental hazard and exposure can be successfully assessed within an AA. Finally, we disagree with Dr Ashford’s concept that responsible entities should put forward three alternatives for a department decision. Rather we have repeatedly supported DTSC’s position that the choice of which alternative to use is solely within the domain of the responsible entity.

**Reviewer Comments on the use of chemical lists to produce the initial Chemicals of Concern (CoC) list [section 69502.2]**

GMA has advocated for the use of a science-based approach that evaluates hazards and the potential for exposure in identifying a narrow set (100-200) Chemicals of Concern for the initial focus of the program and describing others as “Chemicals of Interest”. GMA provided a specific proposal on prioritization decisions which would be more quantitative in nature and not qualitative.

<http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/GCDocsInfo.cfm>

A number of reviewers reinforced these concepts in their comments. Dr Renn called for a “more systematic approach to prioritization of chemicals and products”, suggesting “prioritization of chemicals and products should follow a quantitative approach via a risk characterization scheme and that doing so will enable the Department to take appropriate action”. Dr Gray states that naming all chemicals on 23 lists as CoC will result in the failure to focus this effort, but rather a prioritization process is needed to focus the list of lists into a smaller more refined list. Dr Renn indicates the likelihood that the harm is experienced, the seriousness of this harm and the sensitivity of the endpoints are important factors to consider in prioritization and Dr Gray similarly suggests using chemical potency and levels of human and environmental exposure as a much better process for identifying CoCs as well as priority products. Dr Gray correctly points out that CoC should be those that “pose a significant risk... to consumers”. Dr Sass reinforces that DTSC should consider adverse impacts and exposure “so as to consider real world risks in prioritizing chemicals.” Dr Hattis states that exposure pathways and intake fractions are very different across different uses of the same chemical; this can readily be addressed in product prioritization simply by modeling the potential for exposure from the product in which the chemical is used as recommended in GMA’s proposed ranking approach.

We don’t agree with Dr Applegate’s wholehearted approval of all lists. More importantly, however, the point that Dr Bennett mentions regarding developing a “screening list” from which a more focused CoC list should be developed that considers the potential for exposure should not be overlooked. We disagree with Dr Sass on the topic of adding two additional lists to the 23 that DTSC has proposed. All IRIS chemicals should NOT be included in the initial list. A desire by the Department to identify chemicals with neurotoxicity hazard traits was what led to the industry recommendation for this limited use. IRIS chemicals with carcinogenic hazard traits are already included; the remaining chemicals would be those with repeat dose hazard traits, straying away from the initial DTSC focus primarily on CMR/PBT chemicals. In addition, all chemicals on the EPA contaminant candidate list (CCL) for drinking water should NOT be included. As opposed to regulated chemicals with MCL’s, these are chemicals that EPA is considering for regulation. Adding the CCL would be completely out of step with the other 23 lists that DTSC has selected.

Dr Bennett suggests automatically regarding as reliable all peer-reviewed literature. Best practice in regulatory agencies around the world is to subject all studies to evaluation for reliability and to use them in a weight of evidence approach. GMA has discussed these point in detail in previous comments to DTSC. Contrary to Dr Bennett’s suggestion to include “emerging chemicals” with limited data into the SCP effort, GMA supports DTSC’s inclination to focus on chemicals with available data as alluded to repeatedly over the course of multiple iterations of the draft rule.

Finally, we disagree with Dr Sass that there is a need for a requirement to update the CoC list (the full “Chemicals of Interest List” as envisioned by GMA) on a fixed periodic basis. Dr Farland came to the opposite conclusions, saying “the use of broad lists can help to minimize the need for list updates in the early years of the program and that the list addition/removal processes are adequate for changes over time.” GMA believes that as underlying lists get updated, that will become known. Also, as Petitions for additions to or deletions from the list get reviewed and granted, there will be a number of chemicals to consider. Under the proposed regulations, DTSC is establishing a more focused list of CoC (~200). It could make sense to update that focused list on a schedule similar to that of the development of new Priority Product/CoC pairs.

**Reviewer Comments on the use of initial and key product prioritization criteria to identify consumer products containing CoCs as potential and high Priority Products [section 69503.2]**

GMA has advocated against a narrative approach for prioritizing products and instead, employing a quantitative approach to product prioritization that evaluates levels of hazard and exposure to identify high priorities, focusing initially on a narrow set of Priority Product (PP)/Chemical of Concern (CoC) pairs. GMA provided a specific proposal on prioritization decisions which would be more quantitative in nature and not qualitative.

<http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/GCDOcsInfo.cfm>

There is overwhelming support from reviewers reinforcing these comments. Dr Renn called for a “more systematic approach to prioritization of chemicals and products”, suggesting “prioritization of chemicals and products should follow a quantitative approach via a risk characterization scheme and that doing so will enable the Department to take appropriate action”. Dr Renn indicates the likelihood that the harm is experienced, the seriousness of this harm and the sensitivity of the endpoints are important factors to consider in prioritization and Dr Gray similarly states that using chemical potency and levels of human and environmental exposure to be a much better process for identifying CoCs as well as priority products. Dr Applegate states that priorities should depend on the “degree of potential hazard and the amount of potential exposure”. Dr Christensen states that priorities should be set based on a quantitative assessment of exposure probability and potential consequences of exposure to the public, sensitive groups and the environment.

Dr Bennett raises the point that where a chemical is used in multiple products, DTSC’s prioritization should be targeting the product(s) that drive the majority of the exposure. Dr Gray reinforces Dr Bennett’s point, stating that how widely a product is used is not a good surrogate for exposure. These comments go together with Dr Bennett’s comment that DTSC should not be counting and prioritizing based on the number of routes of exposure, Dr Applegate’s comment that it would be over-inclusive for exposure analysis to be based on mere presence, and Dr Gray’s reminder that the fact of detection in biomonitoring is not a good surrogate for exposure.. Rather, it is the total magnitude of exposure that should be considered in comparison with the hazard level. This is where modeled estimates of the exposure from products should be used to identify the magnitude and contribution to exposure of different products in prioritization decisions. A way to accomplish this concept is elaborated in GMA’s recommendations on prioritizing products.

There were a number of reviewer comments on specific priority setting aspects that must be noted by DTSC as it employs a scientific process in selecting priority products. Dr Applegate states that DTSC should consider aspects of products that reduce or control exposure. Dr Bennet’s comments that exposure modeling, including indoor and dermal exposure modeling as

well as the use of monitoring information will be helpful to DTSC in taking a quantitative approach. Such approaches are regularly used in regulatory and industry safety assessments. One caution that we would make is that when available, reliable monitoring (measured) data is preferred to modeled information in best regulatory practices. We agree with Dr Locke that looking at exposure distributions can be useful in more refined assessments, however that level of analysis is probably not needed in making priority setting decisions on a relative ranking basis. Dr Gray cautions DTSC that the ability to rigorously address aggregate and/or cumulative effects is very difficult and points out that different NAS reports have provided different definitions of 'cumulative' suggesting that this is still unsettled science.

Dr Farland comments that there should be an "internal consistency" step in the priority setting process and that it should be transparent in Department decisions. That advice is critical, particularly if DTSC moves forward with a narrative standard, which is ultimately subjective and could drive a political, not scientific, basis for prioritization. Rather a quantitative approach to prioritization is a pathway to a more scientifically sound process.

Dr Farland also makes an excellent point in cautioning DTSC on the danger in choosing a priority product/chemical of concern based on "readily available safer alternative that is functionally acceptable and technically and economically feasible". It is unlikely that the Department will have access to the complete range of A – M information that is specific to the responsible entity and it's existing product to be able to make such a unilateral decision.

Dr Sass notes that market and sales information used in prioritization should be shared with the public. While this information may prove useful in prioritization, the Department needs also to consider its trade secret potential. This information can be among the most important confidential business information and as such will likely be claimed as trade secret in cases where it is provided by businesses

**Reviewer comments on the principles that will be used to develop the Alternative Analysis Threshold [section 69503.5]**

GMA has advocated for setting a "*de minimis*" or "AA Threshold Concentration" at a level consistent with protective scientific standards set elsewhere in federal and international chemical control systems, an approach that would provide critical regulatory certainty to the marketplace.

Dr Farland raises serious scientific concerns and practical difficulties on the issue of setting an AA Threshold based on the stated principles and that DTSC may well be laying out a process that it does not have the capability to deliver on. We agree with his point that it is unclear what justification would exist to have any separation from a determination of *de minimis* risk. We also agree that DTSC is setting a policy-based decision and not a science-based in its approach to the AA Threshold that has nothing to do with improving public health and the environment for California. The fact that these are not well or fully discussed in the ISOR make this an area for significant improvement before finalizing the regulations.

GMA also has some comments on specific Reviewer points. Dr Applegate suggests that Proposition 65 is a good model for SCP. GMA respectfully disagrees, in that Prop 65 is completely different in scope and intent. Dr Ashford suggests that a threshold exemption should not be available for chemicals that are carcinogens, mutagens, teratogens and endocrine

disruptors. This point of view is at odds with all global regulatory systems, which do employ a *de minimis* or threshold exemption for such substances. Dr Bennett suggests removing “unintended contamination below analytical limits of detection” It’s not clear how this could be accomplished or measured and thus it should not be a factor in DTSC’s decision weighting. Dr Farland states that the Department must give consideration to situations where it is not technically or economically feasible to remove contaminants. That is clearly a reasonable accommodation in cases where there is not a product safety concern.

**Reviewer comments on the definitions of various “adverse” impacts and general usage of the term “adverse” impacts enabling a determination that is adequately protective of public health and the environment.**

GMA has advocated for employing scientifically adequate definitions for “adverse impacts”, “reliable information” and “reliable information demonstrating the occurrence of exposure” and has emphasized the application of weight of evidence evaluation in Department and regulated community decisions.

Dr Locke references the NRC’s 2007 definition of “adverse effect”, which was adopted by OEHHA in its Chapter 54 Hazard Traits Rule. Dr Farland goes on to make the case that the Department should adopt a much more nuanced approach on its definitions regarding adverse impacts. The concept of “adverse” versus “adaptive” responses to exposure, explored in the NRC’s report have been furthered in the scientific literature as discussed by Dr Farland. In particular, DTSC must consider the concept of “relevant responses for regulation” and how it should be incorporated into SCP. This is reinforced by Dr Applegate, who states that the proposed regs do not sufficiently distinguish between differing degrees of harm via adverse impact and that the definitions are broad and NOT parallel. Dr Renn also states that adverse impacts should consider what he calls potential harm, and that the likelihood of harm via exposure must be considered. Dr Gray states that adverse impacts should be related to actual outcomes. GMA agrees with these and must consider exposure and the potential for harm. Finally, Dr Applegate and a number of others note that the air impacts definition lists specific chemicals instead of defining the adverse impacts in air that might result in specific chemical identification.



**RUBBER**  
manufacturers  
association

1400 K Street, NW • Washington, DC 20005 • tel (202) 682-4800 • fax (202) 682-4854 • www.rma.org

January 4, 2012

Deborah O. Raphael  
Director  
Department of Toxic Substances Control  
1001 I street  
P.O. Box 806  
Sacramento, California 95812

**Re: External Scientific Peer Review Reports for the Scientific Basis of the Regulation for Safer Consumer Products**

**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 July 2012 Proposed Safer Consumer Products 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 external scientific peer review reports for the scientific basis of the July 2012 proposed California Safer Products regulation (July 2012 Proposed Rule). Cal. Code Regs. Tit. 22, § 55 (2012). We thank the California Department of Toxic Substances Control (DTSC) in advance for consideration of these comments. RMA urges DTSC to take the time necessary to revise the July 2012 Proposed Rule to make it feasible for manufacturers.

**I. John S. Applegate**

**A. "The second part of the peer review issue references the "key prioritization factors" (§ 69503(b)) that go into the Priority Products List. Here, the regulations opt for simplicity, and they essentially reference hazard and exposure, the key elements of human health and environmental risk. This seems eminently sensible: placement on the priority list should depend on the degree of potential hazard and the amount of potential exposure. If either is very low, the product or product type is not worth pursuing, especially in a resource-constrained environment." (Page 3 of 13).**

**"In CCSPAR, however, risk is not required to be quantified, and so adoption of a risk-based approach usefully limits regulatory action to products that have the greatest likelihood to do the greatest harm. Similarly, the process**

**for establishing the alternatives analysis threshold exemptions (formerly the *de minimis* exemption) serves to focus regulatory and compliance efforts on chemicals and products that are most likely actually to pose a risk based on either the amount of hazardous material or the degree of exposure (§ 69503.5(a)-(d)).” (Page 9 of 13)**

RMA agrees that products or product types that contain a very low amount of a chemical of concern, or that have a low potential for exposure should be excluded from the requirements of the final Safer Consumer Products regulation. Excluding products or product types that contain chemicals of concern in very low concentrations, and that have a low potential for exposure will enable DTSC to focus on priority products that pose the greatest risk which is envisioned by the statute (AB 1879, 2008). Previous 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. RMA strongly supports the inclusion of a default Alternative Analysis Threshold for all chemicals. Specifically, we recommend that DTSC include a default Alternatives Analysis Threshold Exemption of 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence. Additionally, we recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit the same hazard traits or environmental/toxicological end points.

This approach is consistent with other Federal and International regulations established by The Occupational Health and Safety Administration’s (OSHA) Hazard Communication Standard requirements for development of Material Safety Data Sheets (MSDSs), the Environmental Protection Agency’s (EPA) Toxic Release Inventory (TRI) program and the European Union’s Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), that set a fixed *de minimis* level at 0.1% by weight, for individual chemicals. *See* Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988). For example, the EPA has established *de minimis* levels for the TRI program with a base *de minimis* level set at 0.1% for any non-PBT chemical and OSHA-defined carcinogens. Additionally, allowing for the default Alternative Analysis thresholds to be lowered or raised is consistent with the EU’s Globally Harmonized System of Classification and Labeling of Chemicals which establishes chemical-specific thresholds that may be lower or higher than 0.1% based on sound science and reliable information.

RMA also strongly recommends that the final regulation should be limited to intentionally-added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified.

## **II. Nicholas A. Ashford**

- A. “Page 63, lines 31-32: limiting the listing of some of the possible endocrine disrupting chemicals to those produced in amount exceeding 1000 tons per year is unnecessarily permissive. Very low concentrations of endocrine-**

**impacting chemicals pose serious risk, so this large volume trigger in the classification is unjustified on public health grounds.” (Page 1 of 5)**

RMA recommends that DTSC focus the Safer Consumer Products regulation 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 support DTSC’s decision to limit the listing of some possible endocrine disrupting chemicals to those in amounts exceeding 1000 tons per year, and disagree with the comment made by Nicholas Ashford to include listing chemicals of concern produced in amounts below 1000 tons per year. Chemicals produced in amounts below 1000 tons per year are likely to be new chemicals or limited in use. As a result, there may be few or no chemicals available for substitution of the chemical produced below 1000 tons per year. Limiting the listing of some possible endocrine disrupting chemicals to those in amounts exceeding 1000 tons per year will enable DTSC fulfill the intent of the statute; to focus on the chemicals that pose the greatest risk to human health and the environment. (AB 1879, 2008; SB 509, 2008).

- B. “Page 23, section 69502.2b(4), line 41. Being able to classify as a chemical of concern on the basis of the availability of a safer substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, I would expand the ‘substitution availability’ to include ‘use of a safer technological or administrative approach that delivers a comparable functional purpose’. The substitution criteria should not be restricted to chemical substitutes. Recommendation: insert the words “safer technological or administrative approach that delivers a comparable, but safer functional purpose or” before the words ‘availability of’ at line 42.) (Page 2 of 5)**

RMA supports the expansion of the “substitution availability” to include not only chemical substitution, but also the “use of a safer technology or administrative approach that delivers a comparable functional purpose.” (Ashford, Page 2 of 5). Although consideration of technology or administrative approaches for facilities located outside the state of California is beyond the scope of DTSC’s jurisdiction, we recommend that DTSC consider this information as possible criteria for delisting priority products. Changes in technology or administrative approaches that reduce or eliminate the risk of exposure to the chemical of concern in the products should be considered by DTSC in deciding whether a chemical of concern or priority product should be delisted in response to a petition to delist a chemical or product.

- C. “Section 69503.5 should adopt a similar approach. The following text should be added – as a new section 69503.5(f) at page 32, line 30, to the regulation and explained in the statement of reasons: (f) The threshold exemption will not be available in the case of carcinogens, mutagens, teratogens, and endocrine disrupters if a safer substitute technology – including a technological or administrative approach or a substitute product – is available and offers reasonably similar functionality.” (Page 3 of 5)**

Chemicals contained in priority products that are carcinogens, mutagens, teratogens, and endocrine disrupters may pose no risk to human health or the environment as contained in the priority product. The presumption that the chemical or product is subject to regulation by the mere presence of a carcinogen, mutagen, teratogen or endocrine disrupter, abandons risk management principles because it automatically assumes exposure and risk. We agree with Peer Reviewer John S. Applegate's statement that the inclusion of an alternatives analysis threshold will focus regulatory and compliance efforts to products and chemical combinations that are most likely to pose risk.

As discussed previously in these comments, RMA recommends that the final Safer Consumer Products regulation include an Alternatives Analysis threshold with a default level 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence to provide consistency with other Federal and International regulations. *See* Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988). We recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit the same hazard traits or environmental/toxicological end points. RMA also recommends that the final regulation should be limited to intentionally-added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified.

**D. Page 44-45 of the regulations (section 69505.4 Alternatives Analysis: Second Stage, step 3c) last line p. 44: replace “the alternative” with “the three best alternatives” in the statement of reasons: Page 118, line 21: replace “the most suitable alternative” with “the three most suitable alternatives.” Insert the following paragraph before the last paragraph that begins on line 24: “Note that regulations [section 69505.4 Alternatives Analysis: Second Stage, step 3c] page 45, line 2 speaks of “comparative analysis”. Comparative analyses (for example of toxicity, persistence, etc.) are much easier to do than a fullfledged analysis of each alternative. Asking the applicant/responder to select three alternatives, rather than select a single alternative, allows the Department to make much more sensible regulatory choices that maximize protection of public health and the environment, and further, this change goes a long way towards enabling the Department to make the best choice, than simply a better choice of technologies and approaches.” (Page 4 of 5)**

RMA does not support a requirement that as part of the Alternatives Analysis process a responsible entity must provide DTSC with three suitable alternative chemical substitutions for a chemical of concern in a priority product. Depending on the chemical of concern, priority product combination a technically and economically feasible alternative chemical may not exist, or there may be fewer than three technically and economically feasible alternative chemicals. Additionally, certain consumer products must meet safety and performance standards as required by other Federal or State agencies. DTSC does not have the manufacturing expertise to determine whether one alternative chemical will perform better than another alternative chemical in a priority product.

All tire manufacturers must self-certify to the National Highway Traffic Safety that all tires sold in the U.S. meet National Highway Traffic Safety Administration Federal Motor Vehicle Safety Standards. Should DTSC require tire manufacturers to use one alternative chemical that may decrease performance or the life of a tire over another alternative chemical that would not affect performance or tire life, this could create a situation where the tire manufacturing industry is unable to comply with the Safer Consumer Products regulation and federal law at the same time. We strongly recommend that DTSC does not require responsible entities to provide DTSC with three suitable alternative chemical substitutions for a chemical of concern in a priority product. RMA also 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; this determination should be made by the manufacturer of a priority product or in the case of manufacturers located outside the U.S., the importer of the product.

### III. Deborah H. Bennett

- A. **“69502.2b1A1 - the text in the initial statement of reasons for this section makes clear that DTSC may also evaluate chemicals that are structurally similar to another compound with a known toxicity profile. This is an important point because such chemicals are often found to have adverse toxicological effects as well. However, in the actual proposed regulations, the text is so short that this point cannot be ascertained from the document. It is not clear to me how these two documents will be used in concert and thus this might not be a problem.” (Page 1 of 5).**

RMA recommends that DTSC focus the Safer Consumer Products regulation 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 do not support evaluation of chemicals that are structurally similar to another compound with a known toxicity profile because this would greatly expand the list of chemicals of concern which will reduce DTSC’s ability to focus on the chemicals and products that pose the greatest risk to the environment and human health.

The initial list of chemicals of concern may contain chemicals that are present in tires. During the manufacturing process the chemicals present in the raw materials used in tire manufacturing undergo multiple chemical and physical changes that modify the composition and concentration of these chemicals. Thus, DTSC should focus on chemicals in consumer products that pose the greatest risk to human health and the environment and should not consider chemicals that are structurally similar to another compound with a known toxicity profile that may pose no risk to human health or the environment as contained in the priority product.

### IV. Norman L. Christensen, Jr.

- A. **“The principles underpinning the departments Alternative Analysis Thresholds are clear and will ensure that approval of alternative chemicals is based on the best available science and technologies. The current wording removes the ambiguity associated with the de minimis concept used in earlier**

**drafts. The threshold is not to be interpreted as a risk/no risk determination.” (2 of 3)**

RMA agrees that the final Safer Consumer Products regulation should contain an Alternative Analysis Threshold. The inclusion of an Alternative Analysis threshold will enable the Department to focus time and resources on products that contain Chemicals of Concern that pose the greatest risk. However we do not support the language in the July 2012 Proposed Rule 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.” Cal. Code Regs. Tit. 22, §69503.5(c) (July 2012).

As discussed previously in these comments, RMA recommends that the final Safer Consumer Products regulation include an Alternatives Analysis threshold with a default level 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence to provide consistency with other Federal and International regulations. *See* Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988). We recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit the same hazard traits or environmental/toxicological end points. RMA also recommends that the final regulation should be limited to intentionally-added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified.

**V. William H. Farland, Ph.D., ATS**

- A. “The Department has expressed the intent to 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. While this process detail is praiseworthy, the implementation of this aspect of the process will be particularly difficult. The data required to demonstrate functional and technical equivalence is unlikely to be readily available for a head-to-head comparison and the ability of the Department to make the hypothetical case in the absence of such information will be limited. Practically speaking, unless the Department can demonstrate its ability to carry out such analyses, it might be prudent to indicate that this process would infrequently come into play in priority setting. Alternatively, if the Department has some examples where the availability of safer alternatives meets these criteria for products, they should be included in the ISOR.” (3 of 6)**

RMA does not recommend that DTSC include in the Initial Statement of Reasons (ISOR) examples of where the availability of a safer alternative chemical meets these criteria for a priority product. RMA questions where DTSC would obtain information that demonstrates that a safer alternative chemical is functionally acceptable and technically and economically feasible.

Tires are highly engineered products. All tire manufacturers must self-certify to the National Highway Traffic Safety that all tires sold in the U.S. meet National Highway Traffic Safety Administration Federal Motor Vehicle Safety Standards. Information regarding whether there is a functionally acceptable and technically and economically feasible alternative should be provided by tire manufacturers, and should not be provided by DTSC or third parties. Again, we do not support the inclusion of examples of where the availability of safer alternatives meets these criteria for a priority product unless the information is obtained from the manufacturer of the priority product.

**VI. George M. Gray, Ph.D.**

- A. “Developing a scientifically appropriate and defensible Chemical of Concern list is clearly necessary and challenging. To identify key candidates for Alternatives Analysis (AA) the goal would be chemicals most likely to pose a significant risk to workers or consumers.**

**I am concerned that the effort to cast a very wide net (expected by DTSC to be – 3000 compounds by combining lists of chemicals developed for other purposes to determine CoCs will fail to appropriately focus this effort.) It is virtually certain that the list will be too large. If everything is a Chemical of Concern then nothing will be a chemical of concern. I believe the prioritization criteria listed in Article 3 are too broad to help without significantly more specificity.” (Page 3 of 7)**

RMA agrees that the broad list of chemicals that DTSC is expected to compile will fail to focus the July 2012 Proposed Rule on the chemicals that pose the greatest risk. We agree with Dr. George M. Gray that “if everything is a chemical of concern nothing will be a chemical of concern.” The enacting statutes AB 1879, 2008 and SB 509, 2008 specify that the first step of the Safer Consumer Products regulation must be to identify and prioritize chemicals of concern in consumer products. The process for prioritizing chemicals must be based on exposure as well as hazard and must avoid duplication and conflicts with other Federal and State regulatory requirements.

- B. The identification of the opportunity for public health or environmental risk reduction as a prioritization factor (§69503.2(b)) is very sensible. However, using these criteria will require combining both hazard and exposure in a way that is not specified. How widely a product is used in a poor surrogate for exposure because it is obvious that there will be situations in which a chemical of concern is present in a product in a way that will have little or no human or environmental exposure potential and cases with serious exposure potential. (Page 5 of 7)**

RMA strongly agrees that how widely a product is used is an inappropriate surrogate for exposure. Tires are widely used in the United States. However, the wide use of tires has little to do with whether the chemicals in tires are present in quantities that cause harm, and are available

for exposure. We recommend the final regulation place a greater emphasis on risk than on exposure.

During the manufacturing process the chemicals present in the raw materials used in tires undergo multiple chemical and physical changes that modify the composition and concentration of these chemicals. Thus, the original chemical ingredients used to make the tire may no longer be present, or are found at concentrations much lower than the original formulation, and are bound into the rubber matrix that does not allow a risk of exposure to the chemical of concern in the priority product.

**VII. Dale Hatis, Ph.D.**

- A. “The definition of an “alternative” in the “alternatives analysis” might be slightly expanded to include a technology substitution that would make the product type being considered unnecessary. For example, wrinkle free men’s business suits not requiring dry cleaning might be a reasonable substitute in this sense for dry cleaning chemicals.” (Page 10 of 13)**

RMA supports the expansion of the “substitution availability” to include not only chemical substitution, but also the “use of a safer technology or administrative approach that delivers a comparable functional purpose.” However, consideration of technology or administrative approaches for facilities located outside the state of California is beyond the scope of DTSC’s jurisdiction. Again, we recommend that DTSC consider as a possible criteria for delisting chemicals of concern or priority products, changes in technology or administrative approaches that reduce or eliminate the risk of exposure to the chemical of concern in the product.

**VIII. Paul A. Locke**

- A. “The Department will be evaluating numerous CoCs in many Priority Products, and it is not clear that there are suitable laboratory analytical methodologies for CoCs under these diverse scenarios. Furthermore, some of the available methodologies may be relatively insensitive and thus not be able to detect the CoC at a public health or environmentally relevant level, even though it is known to be incorporated in the Priority Product. A better approach would be for the Department to evaluate first whether available laboratory analytical methods for CoCs are sensitive enough to detect CoCs at or below levels that have the potential to create a public health or environmental risk. If the answer to that question is no, then the Department should NOT set the detection level as the CoC’s threshold. Another descriptive method should be developed, based perhaps on modeling and fate and transport of the CoC as it is released from the Priority Product into the environment. This approach can be incorporated into the current draft of the regulations by changing the provision at line 5, page 32 of the Text of the Proposed Regulations (Appendix 4) to read:**

**“(3) Notwithstanding paragraphs (1) and (2), the Department may specify ...{strike out (A), thereby including (B) in this paragraph.}**

**This section also stated that in the event that a Priority Product contains multiple CoCs that exhibit the same hazard trait or environmental or toxicological endpoint, the Department can specify a single alternatives analysis threshold that applies to the total concentration of the CoCs in the Priority Product. This approach is acceptable for 2 or more chemicals whose effects are known or suspected to be additive. However, there are combinations of chemicals whose joint affect might be multiplicative (or more than additive). Moreover, the CoCs might have a common toxicological endpoint, but different potencies. In such cases, the regulations should have flexibility to accommodate a non-additive way of combining these multiple CoCs. In addition, this section of the regulation should also cover situations in which a Priority Product has two or more CoCs that do not exhibit the same hazard trait or endpoint (eg., a compound that can cause both reproductive effects and cancer).” (Page 5 of 7)**

As discussed above, RMA strongly supports the inclusion of a default Alternatives Analysis Threshold rather than a process that identifies an Alternatives Analysis Threshold on a chemical by chemical basis. Again, as discussed previously in these comments, RMA recommends that the final Safer Consumer Products regulation include an Alternatives Analysis threshold with a default level 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence to provide consistency with other Federal and International regulations. *See* Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988). We recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit the same hazard traits or environmental/toxicological end points. RMA also recommends that the final regulation should be limited to intentionally-added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified.

## **IX. Ortwin Renn**

- A. “Another problem is the sections with the reason for exemption. If a chemical poses a serious threat to human health or the environment (line 31 to 40), it may not be sufficient to grant an exemption if the chemical has been used frequently or is part of a natural ingredient.” (Page 3 of 7)**

RMA recommends that the final regulation should be limited to intentionally added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified. Tires contain many ingredients that are from natural sources (talc, metals, natural and renewable oils) whose composition varies depending on factors that cannot be controlled by tire manufacturers. As a result, it is impossible for tire manufacturers to know the exact composition of the natural sources used in the manufacturing process. A requirement to test each natural source for its composition prior to using the material

would be prohibitively expensive and time-consuming. RMA recommends that the final safer consumer product regulation should either be limited to intentionally added chemicals or set a concentration-based Alternatives Analysis threshold limit that exempts chemicals not intentionally added, unless DTSC demonstrates a significant risk.

Additionally, as mentioned previously in these comments RMA recommends that the final Safer Consumer Products regulation include an Alternatives Analysis threshold with a default level 0.1% for all chemicals and allow for the default value to be lowered or raised based on sound scientific evidence to provide consistency with other Federal and International regulations. *See Hazard Communication, 77 Fed. Reg. 17574 (March 26, 2012) and Toxic Chemical Release Reporting Community Right-To-Know, 42 U.S.C. §372.38(a) (1988).* We recommend that the default Alternatives Analysis threshold should apply to an individual chemical and should not apply to a group of chemicals that exhibit the same hazard traits or environmental/toxicological end points. RMA also recommends that the final regulation should be limited to intentionally-added chemicals to enable DTSC to focus on the chemical and product combinations that pose the greatest risk and are easily identified.

**X. Jennifer Sass, Ph.D.**

- A. “Inclusion of markets and sales data is a very good idea, and will prove useful for developing chemical distribution information. As much as possible, this information should be made public so that it can be used by other federal, state, and local officials, scientists, medical professionals, and advocacy groups. For example, it may be useful to epidemiologists looking at potential relationships between product exposures and health impacts, or for unions and worker advocacy groups looking at the prevalence of various cleaning products likely to be used by janitorial staff across the state. While these are just hypothetical examples, they are suggestive of the ways that these data may be useful to the public.” (Page 3 of 4)**

RMA does not support the inclusion of markets and sales data in the Safer Consumer Products rule. External Peer reviewer Dr. George Gray indicates that “how widely a product is used is a poor surrogate for exposure because it is obvious that there will be situations in which a chemical of concern is present in a product in a way that will have little or no human or environmental exposure potential and cases with serious exposure potential.” We agree with Dr. George Gray’s comment that how widely a product is used does not provide information regarding exposure to a chemical of concern. For example, 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 process. Therefore the chemical ingredients in tires may no longer be present following vulcanization. Thus the widespread use of tires does not provide evidence that there is exposure to chemical ingredients in tires which may no longer be present following vulcanization.

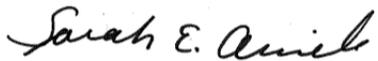
XI. **Conclusion**

RMA again thanks the California Department of Toxic Substances Control for this opportunity to comment on the External Scientific Peer Review Reports for the scientific basis of the regulations for Safer Consumer Products. RMA has continued concern that as written, the July 2012 proposed rule cannot be applied to tires in any feasible way.

As expressed in these comments, we recommend that DTSC revise the July 2012 Safer Consumer Products proposed regulation to: (1) include an Alternatives Analysis threshold with a default value of 0.1% by weight for all chemicals and (2) exclude unintentionally added chemicals from the requirements of the rule. Additionally, as outlined in RMA's comments on the July 2012 Proposed Rule, we also recommend that DTSC revise the July 2012 proposal to: (3) ensure that DTSC responds to petitions to delist a Priority Product before a responsible entity must complete an Alternatives Analysis; (4) harmonize the proposed regulation to enable tire manufacturers to comply with both Federal Motor Vehicle Safety Standards and the proposed regulation; (5) 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 (6) provide a categorical CBI exemption for ingredients in tires.

RMA appreciates your consideration of these comments. Please contact me at (202) 682-4836 if you have questions or require additional information.

Respectfully Submitted,



Sarah E. Amick  
Senior Counsel  
Rubber Manufacturers Association

December 31, 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 External Scientific Peer Review Reports (R-2011-02)

Dear Ms. Von Burg:

On behalf of one of our clients, this letter provides comments on the external scientific peer review reports for which DTSC has provided a comment period from November 30, 2012 to January 4, 2013.

We agree with and consider Dr. Gray's substantive review (pages 2 - 7) important. We particularly agree that the definition of adverse air quality impacts is not scientifically based because having "the ability to result in" an adverse impact is not an adverse impact. Potential effects are not actual effects. We further agree with Dr. Farland's observation that not all impacts observed are "adverse" and that it is important to distinguish adverse impacts from adaptive responses.

We request that DTSC revise the first two lines of section 69501.1(a)(3) of the proposed regulations to read as follows in response to Dr. Gray's input:

(3) "Adverse air quality impacts" means air emissions of any of the air contaminants listed below that ~~have the ability to~~ result in adverse public health, ecological, soil, or water impacts:

Sincerely,



Gary M. Roberts

GMR:ar

**Comments of Unifrax I LLC  
on  
Notice of Public Availability of External Scientific Peer Review Reports  
for the Scientific Basis of the Regulations for  
Safer Consumer Products**

**Department Reference Number: R-2011-02  
Office of Administrative Law Notice File Number: Z-2012-0717-04**

**January 4, 2013**

**Introduction**

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF) and other manmade mineral fiber products, offers the following comments on the published peer review reports on the July 2012 proposed regulations for Safer Consumer Product Alternatives, also known as the "green chemistry" regulations.

On October 11, 2012 Unifrax filed detailed comments on the July 2012 proposal. Those comments, as well as the company's prior comments on the various green chemistry proposals, made the following points among others:

1. Product uses and exposures should be fully considered in the process of setting regulatory priorities and developing alternatives assessments.
2. The Department should rely on existing regulation to the maximum possible extent.
3. In developing potential alternatives both economic and technological feasibility should be considered fully.
4. The Department should rely on sound voluntary product stewardship programs.

Set forth below are quotations supporting these points from the various peer review reports that the Department has now published in conjunction with the proposed regulations.

## **Product Use and Exposure**

John S. Applegate:

Moreover, as the Initial Statement of Reasons explains, one reason for replacing the term “de minimis” in the first version of the regulatory language, with “alternatives analysis threshold,” was to avoid limiting the exemption to trivial risks (p. 103). Thus, like other uses of the protectiveness and feasibility standards, the DTSC is asked to use its judgment to evaluate the seriousness of the risk and to weigh it against the practicality and reasonableness of making changes (p. 4).

Dr. Dale Hattis:

In the light of this substantial disparity there is reason for DTSC to consider chemical X use combinations as the unit of analysis for eventual prioritization. There are disadvantages to this—chemicals authorized for one use may be actually used in other ways. However exposure pathways and intake fractions may be very different across different uses of the same chemical, making it difficult to assess a chemical without making implicit or explicit assumptions related to use types . . . Absent more detailed guidance, it is likely that the comparisons will not be as informative as they might be about the real comparative consequences of using different chemical formulations in the same products, and imperfect or downright counterproductive choices may be made in many cases . . . Overall, if these exposure related factors are omitted from the list, as they currently seem to be, then I am afraid that the prioritization that results and the analyses that are done to determine the “Alternatives Analysis Threshold Exemptions” may neglect some important information affecting risk from specific types of products in specific use applications (pp. 5-7).

## **Reliance on Existing Regulation**

John S. Applegate:

The enumerated evidence for safety (note again that the burden is on the responsible entity) is likewise thorough and reasonable. It lists impacts of special concern in risk (toxicity and exposure) analysis, such as bioaccumulation, cumulative exposures, sensitive subpopulations, and others. Here, too, and consistent with CCSPAR’s practice of avoiding duplication of others’ effort, the regulations are prepared to adopt (or at least consider) pre-existing thresholds ((c)(3)(H))(p. 5).

It cannot be doubted that the safer products legislation and the CCSPAR envision a major undertaking to identify potentially dangerous chemicals, identify the products containing COCs, and take appropriate regulatory

action. There is not, as far as I am aware, a major additional funding stream to support these activities, nor does it seem likely that large amounts of general state funds will be available. Therefore, the CCSPAR must use existing resources as much as possible . . . First, the CCSPAR make extensive use of existing data, rather than seeking to generate data specifically for this regulatory regime. The most important aspect of using others' data is the adoption of the lists of chemicals of concern from other regulators, other California and federal regulatory regimes, and indeed other countries (§ 69502.2). (A related instance is the use of existing regulations to define "adverse impacts" (§ 69501.1(3)-(10)).) This makes great sense, since (as noted above) there are many existing regimes for chemical regulation (p. 8).

Dr William H Farland

The regulation is explicit in its desire to use both hazard (potential for adverse outcomes) and exposure in its decisions making. In addition, it will use availability of information as a criterion. More, and more specific, available information on the COCs in the context of the product leads to a higher priority for listing. Also, the degree to which other state or federal regulatory programs would mitigate the concerns raised by the criteria discussed above would affect product priorities.

While Unifrax agrees with Dr. Farland's statement concerning reliance on other regulatory programs, we caution against undue reliance on the volume of data available as a primary criterion for setting priorities. While we realize that chemicals with available data are logical candidates for early review, the focus should not be on the quantity of the data but on the results produced to date. Simply because a chemical has been extensively studied does not mean that it should be a high priority for regulation. The results of the studies and the effectiveness of related protective measures should determine the regulatory priority. To do otherwise would penalize those who have studied their products most extensively and waste regulatory resources that should be allocated to other, potentially more dangerous products.

Dr. Dale Hattis:

The initial list of Chemicals of Concern is reasonably assembled from sets of chemicals evaluated for important types of toxic effects by other governmental entities. This is a quite sensible starting point, as it makes use of extensive work done by previous expert evaluators. DTSC does not need to “reinvent the wheel” (p. 3).

### **Consideration of Feasibility**

John S. Applegate:

Subsection (c) is concerned with feasibility. It lists several ways in which a CoC can come to be contained in a product . . . This is the kind of balancing that any sensible regulatory system must do, and the conclusion here is eminently justifiable. Likewise, the specific provision for detection limits ((c)(2)) is reasonable; it considers feasibility not only in manufacture, but also in enforcement (p. 5)

Dr Deborah H. Bennett

The first part of section 69503.5 is very reasonable, and I feel it is important to consider both the technical and economic feasibility of removing contaminants. However, section 69503.5c3 is either not clearly written or may result in thresholds that are not reasonable, it is unclear which is the case. The introductory section of this text indicates that a threshold different from what would be developed under paragraphs 1 and 2 could be developed following a listed set of criteria. In considering many of the criteria, one would imagine the agency would lower the threshold, while in some, one would imagine the agency would increase the threshold. While the reasons for lowering the threshold are all very valid, it is not clear how that would be weighed against the technical difficulties related to removing things such as unintended contamination or level set below analytical method limits of detection. More guidance should be provided to understand how these two competing factors would be weighted (p. 4).

### **Reliance on Product Stewardship**

Dr. Nicholas A. Ashford:

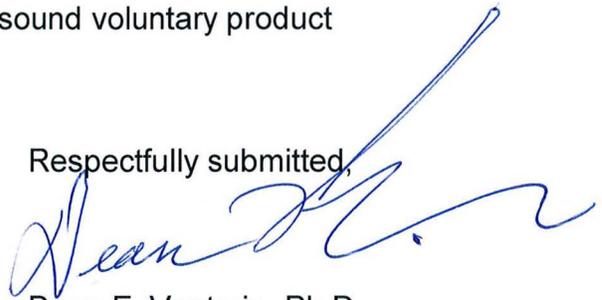
Being able to classify as a chemical of concern on the basis of the availability of a safer substitute is extremely important and should be retained. This ties together risk assessment and alternatives assessment. However, I would expand the ‘substitution availability’ to include ‘use of a safer technological or administrative approach that delivers a comparable functional purpose’ (p. 3).

## Conclusion

As discussed above, the peer review reports provide additional support for the following points in prior Unifrax comments:

1. Product uses and exposures should be fully considered in the process of setting regulatory priorities and developing alternatives assessments.
2. The Department should rely on existing regulation to the maximum possible extent.
3. In developing potential alternatives both economic and technological feasibility should be considered fully.
4. The Department should rely on sound voluntary product stewardship programs.

Respectfully submitted,



Dean E, Venturin, Ph.D  
Director, Health Safety and Environment  
UNIFRAX I LLC



Western States Petroleum Association  
Credible Solutions • Responsive Service • Since 1907

**Catherine H. Reheis-Boyd**  
President

January 4, 2013

Via email – [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Ms. Debbie Raphael ([draphael@dtsc.ca.gov](mailto:draphael@dtsc.ca.gov))  
Director, Department of Toxic Substances Control  
1001 I Street,  
Sacramento, CA 95814

Re: Proposed Safer Consumer Product (Green Chemistry) Regulations

Dear Ms. Raphael:

The Western States Petroleum Association (WSPA) is a trade association representing twenty-seven companies that explore for, produce, refine, transport, and market petroleum and petroleum products and natural gas in California, Arizona, Nevada, Hawaii, Oregon and Washington. Our companies have extensive operations within California and are affected by the regulations currently proposed by the Department of Toxic Substances Control (DTSC).

Because of the impacts on WSPA members and the economy, WSPA has been an active participant in the public policy discussions about the implementation of DTSC's Safer Consumer Product Alternatives Regulations (Safer Consumer Product Regulations) and submitted comments to you throughout the process of developing the Safer Consumer Products Regulations (October, 2010; November, 2010; October, 2012).

In our continuing effort to assist in identifying key issues or concerns that must be addressed in the future, we are providing comments on the structure of the overall program and more specific comments that relate to specific program requirements or components.

## Comments on Overall Scope of the Proposed Regulations

We understand that the primary goal of the Safer Consumer Product regulations is to incentivize manufacturers of consumer products in order that they would provide “safer” products for use by the consumer or within the environment. We understand that the intent is to accomplish this objective by making incremental improvements in product design.

We support the DTSC’s primary reliance upon market forces, rather than a costly command and control approach. We agree with DTSC’s belief that the State can achieve this goal in a timely and cost-efficient manner because open markets are efficient in quickly reflecting consumer preference. Therefore we think it essential that the Safer Consumer Product regulations preserve and enhance consumer choice to allow market forces to drive product innovation and improvement.

In order for the market forces to effectively act through product research and development, we believe predictability of regulation and assured protection of investments in products are necessary to encourage manufacturers to enter the marketplace and invest their resources in a process that is intended to continuously and incrementally progress toward “safer” products. In other words, product manufacturers and formulators will find it difficult to commit resources towards further improvement of products to meet the requirements of the Safer Consumer Products regulations if they are working under a regulatory framework that does not permit a predictable outcome as to what defines a “safer product”.

Recommendation: In revising the proposed regulations, we request the DTSC to carefully consider the three prohibitions set forth at Health & Safety Code §§ 25257.1(b) and (c) that are intended to assure the DTSC limit the scope of the Safer Consumer Product regulation and its enforcement to those products not already subject to regulation by other agencies.<sup>1</sup> Doing so will conserve the resources of the DTSC and regulated entities while avoiding potential conflict with other regulatory programs.

## Comments on Program Details

We agree with DTSC’s determination that review of the Safer Consumer Product regulations is warranted by Health & Safety Code § 57004. However, we believe that this review could have been improved by notifying stakeholders prior to initiating the review in order to allow their input. Another problem that could have been remedied with prior notice to stakeholders is to increase the diversity of reviewers and selection of qualified people to perform the review. Currently, all the reviewers appear to be academically-trained with limited hands-on experience in the areas of product design, specification or manufacturing.

Recommendation: Experts irrespective of affiliation should be added as panelists in a review of products. For example, scientists with industrial and manufacturing experience should be chosen just as reviewers have been chosen representing non-governmental entities that have advocated for more stringent consumer product regulation. Specifically, a number of reviewers with experience in

---

<sup>1</sup> Health & Safety Code §§ 25257.1(b) and (c) 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.

industrial research and development, and with responsibility for assuring compliance with regulatory programs governing consumer products should be included.

As part of our recommendation, the choice of Mr. John Applegate, “to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices”<sup>2</sup> needs to be augmented with other experts as noted above. While it is clear that Mr. Applegate has substantial expertise in the area of environmental law, it also seems obvious that additional resources are needed to provide expert opinion on whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

### **Focus of Review Process**

The five issues the DTSC appeared<sup>3</sup> to direct the reviewers to evaluate were: 1) Use of other chemical lists to produce an initial Chemicals of Concern (COC) list, e.g., the “list of lists” approach; 2) Whether use of the criteria in Article 3 is sufficient to identify all types consumer products with COCs as potential Priority Products; 3) Whether the use of the “cumulative concentration” in the proposed regulations to derive an Alternative Analysis Threshold (AAT) for COCs that have the same hazard trait or toxicological endpoint is scientifically understood and adequately protects public health and the environment; and 4) When scientific information is available, can a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment. In addition, a fifth catch-all request was made by the DTSC to include comments on the scientific appropriateness of any other aspect of the proposed regulation.

We believe that the scope of inquiry was too narrow and believe that the inquiry should have addressed other issues. We have prepared suggestions for each of the issues noted above within the recommendations that follow below.

Recommendation: We suggest that other issues be included in the product review process including:

- Whether the process to be used in applying the criteria in Article 3 to all potentially regulated products is based upon sound scientific knowledge, methods and practices;
- Economic impacts of the proposed regulations;
- Applicability to which consumer products;
- Cost effectiveness of the proposed program.

---

<sup>2</sup> Mr. Applegate is very forthcoming regarding his qualifications to make this determination and the focus of his review as he acknowledges on p. 4 “As a non-scientist, I will focus on their coherence as regulation of toxic chemicals.”

<sup>3</sup> Although the reviewers’ comments and their curriculums vitae were posted on the DTSC website, the actual documents provided to each reviewer and associated directives did not appear to be posted on the DTSC website. In addition, the

In making these suggestions, we also make the following comments on reviewer responses to issues that were raised earlier in the process.

1. Use of other chemical lists to produce an initial Chemicals of Concern (COC) list

We do not believe the use of the lists of lists approach is the best means to identify the initial COC list, in part, for the reasons cited by Dr. Gray<sup>4</sup>:

“combining lists of chemicals developed for other purposes to determine CoCs will fail to appropriately focus the effort. It is virtually certain that the list will be too large. If everything is a Chemical of Concern then nothing will be a chemical of concern. I believe the prioritization criteria listed in Article 3 are too broad to help without significantly more specificity.”

This problem of classifying thousands of chemicals as COCs using the list of lists approach has been made by other commenters on earlier versions of the proposed rule. For example, Dr. Klaus Berend, European Commission Fellow at U.C. Berkeley, sought to inform the DTSC of his views of the problem created by the list of lists approach based upon his experience with the European Union Registration, Evaluation, Authorisation, and Restriction of Chemical Substances (REACH) program. In his comments made to the Green Ribbon Science Panel on a prior version of the proposed regulation over three years ago he stated:

“my comment is more on the feasibility of what is envisaged. With the hazard traits that have now been proposed and the lists of lists, **you look at thousands of substances of concern. And one would say if everything is a concern, nothing is of special concern.** So that is something, **a proper prioritization that could certainly be improved.** Same for the selection of the substances then in terms of the exposure. We have the three categories in the proposal, the direct exposure, the exposure at the end of the lifecycle or no exposure. But then the actual obligations that flow from that, the alternatives analysis, are identical for all these three priorities. So maybe that would also be a way to select chemicals for an earlier action compared to others for later action.”<sup>5</sup> (**bold:** emphasis added)

Regrettably, the DTSC chose to disregard Dr. Berend’s comments. We suggest that the DTSC reconsider Dr. Berend’s comments as well as Dr. Gray’s comments in order to adopt a more efficient and effective prioritization process for its Safer Consumer Products program.

Mr. Applegate and Dr. Gray also observed, correctly, that the goal of the prioritization process is to identify those product/COC combinations that truly warrant additional safeguards because they pose a

---

process and criteria for selection of each reviewer is unstated. We believe that more transparency on these issues would be helpful in the future.

<sup>4</sup>See Dr. Gray at p. 3.

<sup>5</sup>Comments by Dr. Berend to the DTSC Green Ribbon Science Panel 10/14/09 at p. 61 lines 13-25 and p. 62 lines 1-3.

significant risk, e.g., implementation of a worst first approach.<sup>6</sup> It would be helpful for the DTSC to keep this in mind as it develops the initial list of Priority Products as well as guidance for deriving AATs and conducting Alternative Analyses.

We share Dr. Gray's skepticism of the use of hazard traits to identify COCs because chemicals may have many adverse effects at different dose levels, in different test systems and in different species. He properly points out the tautology in using bio-monitoring lists to identify COCs, e.g., those COCs subject to bio-monitoring are likely to be duplicative of those COCs already found on at least one of the many other list of lists.<sup>7</sup> We also agree with Dr. Gray's observation regarding the difficulty and relevance in utilizing bio-monitoring data for prioritization purposes<sup>8</sup>:

“§69501.1 (53) (B) The use of bio-monitoring data to demonstrate exposure to a COC seems problematic. There will clearly be sources of exposure (e.g., smoking, diet) that will have nothing to do with consumer products. This information is also unlikely to be useful for identifying and prioritizing CoCs and products.”<sup>9</sup>

Although we appreciate the opportunity to conserve resources by leveraging from work performed by other governmental agencies and bodies, we do not believe the list of lists approach is the best way to proceed.<sup>10</sup> Instead, we suggest the DTSC incorporate the process identified by the Green Chemistry Alliance (GCA) its recent comments to the DTSC.

## 2. Whether use of the criteria in Article 3 is sufficient to identify all types of consumer products with COCs as potential Priority Products

The criteria in Article 3 are numerous, broad in scope, and potentially overlapping. Although it is unclear how they will be used in prioritization, we agree with Dr. Renn's statement:

“Article 3, Section 69503.2 lists more than 40 criteria of high priority. First, this number seems to be too high for being used to prioritize a large list of chemicals. Second, many criteria are redundant. Thirdly, different classification principles have been used to complete the list. It looks like a large laundry list with the intention not to miss anything. I would suggest a more systematic approach to the priority list ...”<sup>11</sup>

---

<sup>6</sup>See Mr. Applegate at p. 10 “With a focus on priorities, an outlet exemption, and heavily judgment-based standards, DTSC is poised to be able to focus its energies on the worst problems and the majority of the problem expeditiously, leaving perfection to a later day.” See. Dr. Gray at p. 3 “To identify key candidates for Alternatives Analysis (AA) the goal would be chemicals most likely to pose a significant risk to workers or consumers.”

<sup>7</sup>See Dr. Gray at p. 4.

<sup>8</sup>See Dr. Gray at p. 7.

<sup>9</sup>*Id.*

<sup>10</sup>We specifically oppose Dr. Sass' request at p.3 of her comments to add the USEPA Contaminant Candidate list to the list of lists as there are an adequate number of chemicals to consider on the myriad of lists identified in the proposed regulation.

<sup>11</sup>See Dr. Renn at p. 2.

We believe the more important issue of the scientific peer review is whether the process and the standard to be used in applying the criteria is based upon sound scientific knowledge, methods and practice. A number of the reviewers expressed similar concerns.<sup>12</sup> It is unclear how the Article 3 criteria will be applied to a single product, let alone the wide range of products found in the marketplace that could potentially fall within the scope of the regulation. At this point, the prioritization process and its output are entirely speculative and it appears to be premature to conclude the criteria in Article 3 will result in prioritization that is based upon sound scientific knowledge, methods and practices.

3. Whether the use of the “cumulative concentration” in the proposed regulations to derive an Alternative Analysis Threshold (AAT) for COCs that have the same hazard trait or toxicological endpoint is scientifically understood and adequately protects public health and the environment.

Responses by the reviewers addressed two aspects of this issue. The first aspect was the responses to the specific use of a COC’s “cumulative concentration” to derive an AAT, and the second aspect related to the factors to be considered in deriving an AAT. With respect to the first aspect, the directive to the reviewers and the relevant sections of the regulation<sup>13</sup> fail to provide an adequate scientific description of “cumulative concentrations” for COCs that have the same hazard trait or toxicological endpoint.<sup>14</sup>

Recommendation: We suggest that the term “cumulative concentration of COCs that have the same hazard trait or toxicological endpoint” be applicable only to those chemicals that produce the same toxicological endpoint through an identical mode of action.

Regarding the second aspect, factors to be considered in deriving an AAT value, the reviewers identified a number of issues. One issue raised by nearly all reviewers was the use of the level of detection (LOD).<sup>15</sup> The apparent decision to consider the LOD as the minimum AAT value, e.g., AAT floor, is correctly identified by Dr. Farland as a policy decision, not a science-based decision. In determining whether this is a reasonable policy decision, it is necessary to consider the objective of the AAT.

We agree with Dr. Gray in that the “Alternative Analysis Threshold Exemption is an important administrative tool for focusing effort and resources.”<sup>16</sup> Default rote application of the LOD for all COC/product combinations without properly considering the other relevant factors in §69503.5 will do

---

<sup>12</sup>See Mr. Applegate at p.3 “What is missing in § 69503(b), as elsewhere in the CCSPAR, is a statement of a clear standard for placement on the list or not.” See Dr. Gray at p. 5 “It is unclear to me how ‘Reliable information concerning public ... exposure to the Chemical(s) of concern...’ can be used to set priorities. ... The identification of the opportunity for public health or environmental risk reduction as a prioritization factor (§69503.2 (b)) is very sensible. However, using these criteria will require combining both hazard and exposure in a way that is not specified.”

<sup>13</sup>§69503.5(c)(3)(G) and (d).

<sup>14</sup>See Dr. Farland at p. 5 and Dr. Gray at p.6,

<sup>15</sup>See Mr. Applegate (p.5), Dr. Bennett (p.4), and Dr. Farland (p.5) considering the LOD as matter of feasibility for enforcement purposes, including concerns with the variability in LOD from one analytical laboratory to another. Both Dr. Ashford (p.3) and Dr. Locke (p.5) would like the AAT lower if warranted based upon health-based endpoints. How enforcement of a standard lower than the LOD could be practically implemented appears to be problematic.

<sup>16</sup>See Dr. Gray at p.5. See also footnote 7 above; Mr. Applegate expresses the same concern at p.10 of his comments.

little in achieving this objective. In other words, if all products within the identified product category having the COC at the LOD are required to undergo a costly and time-consuming Alternative Analysis irrespective of the potential human or ecological hazard of the product, then this is an inappropriate policy decision because it wastes the efforts and resources of both the DTSC and regulated entities.

Recommendation: We suggest that the DTSC consider preparing AAT guidance to better address this issue and improve the efficiency and effectiveness of the Safer Consumer product regulatory program. Furthermore, we do not believe that the additional factors and changes suggested by the other reviewers are warranted.<sup>17</sup>

4. Whether when scientific information is available, a qualitative or quantitative determination of adverse impact can be made, and is adequately protective of public health and the environment.

We concur with those reviewers who expressed concerns regarding the overly broad scope of the term “adverse” impacts, in particular those observations made by Dr. Gray<sup>18</sup>:

- “Adverse effects are actual outcomes”;
- “Adverse air quality impacts as defined (emissions of listed contaminants (§69501.1(a)(3)) are not adverse impacts. They may result in adverse impacts.”
- “Bioaccumulation without consequences is not an adverse effect.”<sup>19</sup>
- “Exceedance of a standard is not an adverse effect. The values used in setting standards (e.g., RfDs) have some degree of conservatism embedded (although the amount is not known). There may be public health consequences above a standard but it is not certain.”

5. Catch-All Comments.

Several reviewers noted the absence of an effective and understandable standard that would allow manufacturers to determine *a priori* what a “safer product” is without DTSC involvement.<sup>20</sup> The best expression of this issue and its drawbacks was presented by Mr. Applegate at p.6:

---

<sup>17</sup> For example, *see* Dr. Ashford at p. 3 regarding unique treatment of carcinogens, mutagens, teratogens and endocrine disrupters; Dr. Hattis regarding intake fraction at p. 7; and Dr. Locke at p. 4 regarding accidents and “overexposures”.

<sup>18</sup> *See* Dr. Gray at p. 6-7.

<sup>19</sup> However, bioaccumulation, as well as other types of impacts, may be a cause for concern.

<sup>20</sup> *See* Mr. Applegate at p. 6; Dr. Gray at p. 7, and Dr. Hattis p. 11,

“Indeed, the real issue with alternatives analysis in Article 5 is not the use of the term ‘adverse impacts,’ but rather the absence of an explicit standard for a responsible entity to choose or reject an alternative (§§ 69505.4(c), 69505.5(j)(2)(B)), or for DTSC to accept or reject the responsible entity’s choice (§ 69505.6(a)-(b)). The Initial Statement of Reasons (p. 140) states that an alternative is to be selected if it is ‘safer’ and ‘viable’ (p. 140), and in fact ‘safer alternative’ is a defined term in the definitions (69501.1(a)(56)). However, that language appears nowhere in Article 5. While the CCSPAR is permeated with evidence-based judgment – and the assumption of Article 5 seems to be that the alternatives analysis will clearly point to the need to adopt a safer alternative (or not) – the absence of a standard for evaluating options seems to be a gap. Requiring a safer alternative appears among the regulatory responses (§§ 69506.6, 69506.9 (prohibition of sales, green chemistry)) if the DTSC disapproves the AA, but this seems at best an awkward way to express a standard, especially since the regulatory response would typically *follow* the unguided disapproval.”

The reviewers noted that the AA process will involve comparing the different benefits and negative impacts of each alternative, requiring the evaluator and DTSC to consider the trade-offs associated with each alternative, and as a consequence, creating the potential for bias and differences of opinion between the DTSC and the evaluator.<sup>21</sup>

**Recommendation:** We agree with many of the comments and share their concerns as well as their cautions regarding the potential for policy bias and subjectivity of values to be inappropriately applied in assessing and identifying the “safest” alternative. We expect the DTSC to carefully consider and address their concerns in the proposed regulation. Lastly, as a practical matter it will be critical for the regulations to have well-defined AA methodology to provide a clear standard so that manufacturers can readily determine *a priori* what a “safer” product is to permit market forces to work efficiently and effectively without DTSC involvement.

---

<sup>21</sup>See Dr. Gray at p.2 addressing policy bias “Good alternatives assessment means there is not a thumb on the scale when we are weighing the risks of different chemicals. See Dr. Hattis at p. 12 addressing the need to acknowledge trade-offs “There should be some admission, however, that sometimes there will be tradeoffs between different kinds of effects (e.g. fetal growth retardation vs. carcinogenesis). In such cases the DTSC must use its best judgment to choose options that, on the whole, produce effects that it considers less significant in endangering public health. P. 155 has a welcome admission that tradeoffs among different types of values are inevitable, and an overall “cost benefit” framework will be applied at the agency’s discretion.” See Dr. Renn at p. 4-5 addressing trade-offs and the subjectivity of values in considering the importance of the impact of each trade-off “Any human action has impacts: so the categorization of consequences of human intervention into beneficial, neutral or adverse impacts requires some value judgment. Often beneficial consequences for one type of endpoints can be detrimental for another type of endpoints. Again one needs to make trade-offs between the two types of consequences”.

We appreciate the opportunity to comment on these issues and look forward to a continuing dialog. Should you have any questions, please feel free to contact me or Mr. Mike Wang ([mike@wspa.org](mailto:mike@wspa.org); cell: 626-590-4905) of my staff.

Sincerely,

A handwritten signature in blue ink that reads "Cathie A. Boyd". The signature is fluid and cursive, with the first name "Cathie" being the most prominent.

cc: Ms. Odette Madriago ([omadriag@dtsc.ca.gov](mailto:omadriag@dtsc.ca.gov))  
Mr. Jeff Sickenger ([jsickenger@ka-pow.com](mailto:jsickenger@ka-pow.com))  
Mike Wang ([mike@wspa.org](mailto:mike@wspa.org))