

GCREgs@DTSC

From: Becky Klawans <hasklaws@mac.com>
Sent: Wednesday, October 10, 2012 9:09 PM
To: GCREgs@DTSC
Subject: Chemicals of Concern

Dear Department of Toxic Substances Control,

I am emailing you to express my support for the law passed in 2008 that requires the state to make a list of chemicals of concern, identify possible alternatives, and regulate the substances to reduce or eliminate public exposure. The public has a right to know what is in the products that they buy or are exposed to and to have them reduced and regulated. Research has shown that chemical substances leach out of plastics, fabrics, and other materials and people ingest them or absorb them through their skin, and that this is especially harmful to the unborn and children. Please regulate and remove toxic chemicals and chemicals of concern and end this type of toxic exposure.

Sincerely,
Becky Klawans



CORPORATE ENVIRONMENTAL EXCELLENCE

October 8, 2012

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

Via Mail and Email: gcregs@dtsc.ca.gov

Dear Ms. Von Burg:

On behalf of Koch Industries, Inc. (KII) and its affiliate companies, we appreciate this opportunity to comment on DTSC's Safer Consumer Products Proposed Regulations, R-2011-02 ("Proposed Regulations"). KII owns a diverse group of companies involved in refining and chemicals; process and pollution control equipment and technologies; minerals; fertilizers; polymers and fibers; commodity trading and services; and forest and consumer products. KII companies have a presence in nearly 60 countries with approximately 70,000 employees – over 1,400 of which are in California. KII has been working with the Green Chemistry Alliance (GCA) and several of our trade associations. KII supports the comments submitted on behalf of GCA, California Manufacturers & Technology Association, American Forest and Paper Association, American Cleaning Institute, American Wood Council, and Grocery Manufacturers Association ("Trade Association Comments") to DTSC on this important issue.

KII fully understands DTSC's desire to promulgate this new regulation as soon as possible. However, the Proposed Regulations as currently constructed are unworkable, fundamentally flawed and may not pass legal review. If DTSC continues to pursue the framework as laid out in the current version of the Proposed Regulations, the effective implementation could suffer major delays while these issues are addressed. Although we are providing our comments to DTSC on the Proposed Regulations as written, KII strongly encourages DTSC to focus on regulatory alternatives, such as the proposal submitted to DTSC by GCA on November 1, 2010, that have a greater chance of being implemented, passing legal review and achieving the stated objectives of the AB 1879. For the record a copy of that early proposal is available at: http://www.greenchemistryalliance.org/Media/DTSC_SCPA_GCA_Comment_Ltr20101101.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1.

Generally, the Proposed Regulations contain four major fundamental flaws that are discussed in more detail in the Trade Association Comments:

- a. **Lack of Clarity:** DTSC's reservation of unprecedented discretion in the decision making process and providing no criteria upon which the regulated industries can determine what DTSC may consider "safer" as a part of the alternatives analysis creates confusion and uncertainty for the regulated community. Based on the plain reading of the Proposed Regulation, there is no way for a regulated entity to understand what is

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- b. required, how to comply, and when or if in the process DTSC will make final determinations.
- c. Conflict with Existing Authorities and Laws: As described more fully in the Trade Association Comments, DTSC's Proposed Regulations are in conflict with existing occupational safety laws, EPA's chemical inventory and review process established by the Toxic Substances Control Act (TSCA), and the authorities provided to the U.S. Consumer Product Safety Commission under the Consumer Product Safety Improvement Act (CPSIA) of 2008. Associations have also pointed out in comments that the Proposed Regulations are in conflict with or attempt to supersede other authorities such as those provided under the Federal Food, Drug, and Cosmetic Act (FFDCA) to the Food and Drug Administration.
- d. Exceeding Authority Granted by Underlying Statute and Preemption: DTSC has exceeded the authority granted to it by the legislature in the drafting of the Proposed Regulations. There are several areas where DTSC has ignored the direction of the statute and gone beyond the authority granted, the Trade Association Comments provide further detail on these areas. In addition, federal law preempts certain aspects of the regulation. KII suggests that DTSC carefully review federal laws and possible preemption, whether express or implied, prior to finalizing the Proposed Regulations.
- e. Inappropriate Intrusion into the Business Decision Making Process, Loss of Proprietary Information, and Competitive Disadvantage: The Proposed Regulation provides for an unprecedented level of intrusion into the confidential business information ("CBI") of the Responsible Entity. One example is the requirement to provide unit margin and marketing information as part of the alternatives analysis. The margins and marketing of a product has no relation to the safety or environmental attributes of a chemical. Requiring the submission of irrelevant information is not only a waste of resources, but where this information will be shared allows for competitors to access sensitive information and benefit from the work, resources, time and knowledge of the first company to submit.
 - Information requests should be limited to that information essential to evaluating and communicating potential adverse public health and environmental impacts of the Chemicals of Concerns and Priority Products.
 - Requests for information concerning pricing, volume, margins, customer lists, supply chain information, manufacturing process information, etc. is unnecessary, inappropriate and could potentially raise anti-trust issues. These requests are made in the name of transparency when in reality they are unnecessary and do nothing to advance the stated purpose of the regulation, that being to provide safer consumer products to the citizens of California.

October 8, 2012

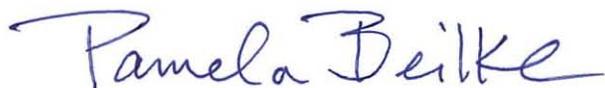
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- The collection and dissemination of this information in a public forum will stifle innovation and remove the incentives for pursuing new products and markets.
- DTSC should simply judge the output of their decision-making process concerning the products that the Responsible Entities wish to bring to market.
- Instead of DTSC, the Responsible Entity should be allowed to self-certify as companies currently do for many existing local, state and federal regulations.
- This intrusion into the Responsible Entity's CBI highlights DTSC's lack of understanding of the realities involved with making important business decisions. Examples of the decisions that seem to be ignored include determining which chemicals should be used in a product, identification of customer acceptance criteria, determining how much to sell a product for, identifying how to protect proprietary information, and figuring out how to communicate effectively with customers. All of these decisions and more are business decisions that can determine whether a product is successful in the marketplace; these are not decisions for DTSC to make.

The Trade Association Comments elaborate on these fundamental flaws and provide specific citations and examples to help DTSC understand why the Proposed Regulation has not met the requirements of the Administrative Procedures Act nor the California Environmental Quality Act. In addition, the Economic Impacts Analysis is inadequate as it failed to fully evaluate the economic impacts of the Proposed Regulations. The economic and fiscal analysis should be completed to include the true costs to California, consumers, and the regulated community.

KII supports and incorporates by reference the detailed Trade Association Comments submitted in response to DTSC's Proposed Regulations. KII encourages DTSC to continue to work with industry to develop workable, practical and legally defensible Proposed Regulations. Should you have any questions, KII would welcome the opportunity to provide further clarification. Please contact our California representative, Dawn Koepke (dkoepke@mchughgr.com, 916-930-1993) for further information.

Sincerely,



Pamela Beilke
Environmental Excellence Manager
KII EHS Excellence

GCREgs@DTSC

From: Sheila Lemons <sheila_lemons@att.net>
Sent: Wednesday, August 01, 2012 3:45 PM
To: GCREgs@DTSC
Subject: Reference Number R-2011-02

Categories: Comment

I am in favor of this bill: Reference Number R-2011-02

State should adopt proposed rules on toxic chemicals.

Thank you,

Sheila Lemons

Got art?

[SLFA Studio](#)

GCREgs@DTSC

From: Levitan, Lynn <LLevitan@crowell.com>
Sent: Friday, August 03, 2012 2:48 PM
To: GCREgs@DTSC
Subject: Preliminary List of Chemicals of Concern?

Ms. Von Burg:
Please advise if there is a preliminary list of Chemicals of Concern available for review.
Thank you,
Lynn

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**Lynn R. Levitan**  
**Counsel**

**Crowell & Moring LLP**

515 South Flower Street - 40th Floor  
Los Angeles, CA 90071

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<http://www.crowell.com/Professionals/Lynn-Levitan>

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## GCREgs@DTSC

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**From:** Robert Levy <robertmlevy@comcast.net>  
**Sent:** Monday, October 01, 2012 8:48 AM  
**To:** GCREgs@DTSC  
**Subject:** regulations

**Categories:** Comment

As a lawyer who has handled many cases over the years and unsuccessfully worked on trying to establish a cause of action arising from the fear of cancer, I can promise you that the only way to obviate fear is to have a government that acts independently of the pressure of the people who earn money from that which can and does harm us. Please do not back down. Impose stringent regulations for the identified chemicals and do not succumb to pressure from those whose interest is economic rather than that of the health and safety of the community. Thank You.

HAVE A GREAT DAY  
Robert Levy



## GCREgs@DTSC

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**From:** Toni Littlejohn <toni@wild-carrots.com>  
**Sent:** Monday, October 01, 2012 10:17 PM  
**To:** GCREgs@DTSC  
**Subject:** On controlling toxic chemicals

Dear Dept of Toxic Substances Control of CA,

It is very important to the future of our state and country that you complete and implement regulations controlling toxic substances.

Thank you,

Toni Littlejohn



## GCREgs@DTSC

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**From:** Nan Lorenzen <nhlorenzen@earthlink.net>  
**Sent:** Tuesday, October 02, 2012 10:00 PM  
**To:** GCREgs@DTSC  
**Subject:** please!

I know you are under hurricane pressure from the chemical industry to weaken the regulations for the 2008 law to protect our health and our environment.

Please, please listen to your conscience and fend off their pressure.

Remember, it is your health and that of your family in jeopardy as well as the rest of us.

Please care!

Thank you,

Nannette Lorenzen



## GCREgs@DTSC

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**From:** Maggie Mahboubian <mmahboubian@roadrunner.com>  
**Sent:** Wednesday, October 10, 2012 12:51 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative

Dear Ms. Von Burg,

I am writing in response to the pending implementation of the Green Chemistry Regulations in the state of California. I have not been able to find a list of the Chemicals of Concern to understand if or how my company will be impacted. I make skincare using GRAS or edible grade ingredients. I also make natural perfumes using essential oils and other naturally derived extractions. Furthermore, the proposed regulations do not contain an exemption or consideration of any kind for small businesses like mine and which could potentially harm me and put me out of business entirely.

Cosmetics are already regulated by the FDA, although various states, including California have been adding legislation that may make it difficult for small, domestic manufacturers to make and sell their products not only in their own state, but across state lines. The FDA already has a list of chemicals that are not to be used. How will this regulation improve on the nationwide law that already exists and why should we have to pay to ensure a law that is already in effect. How will the Green Chemistry Regulations be enforced?

In this difficult economic climate can we afford to continue with over-regulation of an industry (like the cosmetics industry) that has a safe track record? I am a strong advocate of consumer safety, but unclear and over-regulation with the possibility of my not being able to finance the requirements will not make the industry safer. It will simply put me out of business and offer the public fewer alternatives.

Finally, the list is called "Chemicals of Concern", rather than chemicals that have been PROVEN to be toxic. There is a big difference in terms of the science. How can a regulation be formed on the basis of a "Concern"? Why waste taxpayer dollars on legislation that is not proven? I just don't understand this and it seems potentially harmful economically.

Thank you for your attention,  
Maggie Mahboubian

# MARIN COUNTY HAZARDOUS AND SOLID WASTE MANAGEMENT JOINT POWERS AUTHORITY

Belvedere:  
Vacant

October 10, 2012

Corte Madera:  
David Bracken

DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806

County of Marin:  
Matthew Hymel

Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Fairfax:  
Judy Anderson

**RE: Comments on Draft Regulations for Safer Consumer Product Alternatives**

Larkspur:  
Dan Schwarz

Dear Director Raphael:

Mill Valley:  
Jim McCann

The Marin County Hazardous and Solid Waste Joint Powers Authority is a supporter of the development of the Green Chemistry program as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

Novato:  
Michael Frank

Ross:  
Rob Braulik

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

San Anselmo:  
Debbie Stutsman

San Rafael:  
Nancy Mackle

Sausalito:  
Adam Politzer

While we generally support the proposed regulations, we request that you consider the following modifications:

Tiburon:  
Margaret Curran

(1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from the California Product Stewardship Council (CPSC) and local government agencies and the public prior to approving the plan.

(2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions:

Now is the time for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,



Michael Frost  
Executive Officer

Cc: JPA Board Members

*f:\waste\jpa\legislative support\dtsc green chemistry.docx*

**From:** Devi Peri <Devi.Peri@marinsanitary.com>  
**Sent:** Thursday, October 11, 2012 3:44 PM  
**To:** GCREgs@DTSC  
**Subject:** Green Chemistry program

October 11, 2012

DTSC  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806  
Submitted via e-mail to: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**RE: Comments on Draft Regulations for Safer Consumer Product Alternatives**

Dear Director Raphael:

Marin Sanitary Service has long been a supporter of the development of the Green Chemistry program in California as a way to reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year. Many products sold have hazardous constituents and require special handling in order to reduce contamination to storm water, sewer systems and the natural environment that are very expensive to properly manage or remediate. **We support the development of regulations that would promote the re-design of these problem products.**

The U.S. Environmental Protection Agency (EPA) data establishes that 75% of the municipal waste stream is made up of products and packaging. Significant and growing shares of these products contain hazardous constituents, and are banned from the landfill at the end of their useful life. Local government household hazardous waste (HHW) programs have borne the burden of managing these products for many years. Because the HHW programs around the state are identified as the primary collection mechanism, substantial infrastructure and funding are necessary to collect and manage these wasted materials.

While we generally support the proposed regulations, we request that you consider the following modifications:

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website and DTSC should be inviting input from CPSC and local government agencies and the public prior to approving the plan. Our long experience with product stewardship can help DTSC to ensure that product stewardship plans will be efficient and effective.
- (2) Municipality Costs - Add cost to municipalities as a prioritization factor. Removing problem chemicals from products means HHW programs will be managing fewer products. Less management results in a lesser burden on taxpayers and ratepayers. The cost savings could be in the tens of millions.

We believe the time is here for California to meld the best elements of current programs and become a world leader in creating producer responsibility systems that drive green design and add to California's leadership as a wellspring of industrial innovation for sustainability.

Sincerely,

Devi Peri  
Education Coordinator  
Marin Sanitary Service

**Devi Peri**

**Education Coordinator**

*Marin Sanitary Service*

*Marin Recycling and Resource Recovery*

535 Jacoby Street

San Rafael, CA 94901

**415-458-5539**

**Let's make Marin a Zero Waste zone by 2025.**

**Visit [www.zerowastemarin.org](http://www.zerowastemarin.org) to find out how you can help!**

10 October 2012

Debbie Raphael, Director  
Department of Toxic Substances Control  
State of California  
PO Box 806  
Sacramento, CA

Re: Public Comments on the Safer Consumer Product Regulations

Dear Director Raphael,

Thank you for the opportunity to comment on the proposed Safer Consumer Product Regulations. It has been a pleasure to work with you and your staff in the development of these requirements. I thank you for the time, effort, and dedication the staff has put into listening to all of the stakeholders and the hard work it has taken to put together the drafts and revisions for this groundbreaking new step in protecting public health and the environment from chemicals of concern in consumer products.

I strongly support the goals and objectives of AB 1879 and the requirements outlined in the Safer Consumer Product regulations. Overall, I think the department has done an excellent job of balancing the needs and interests of a variety of stakeholders. Rather than addressing the regulations line by line, I have confined my comments to a few key conceptual areas. These comments are offered, not as a criticism of the excellent work done by the department, but as suggestions in the interest of providing additional information and perspective to help achieve better clarity, efficiency, and effectiveness in implementing this important program.

### **Comments—**

**AB 1879:** This bill requires the department to establish (1) a process by which chemicals or chemical ingredients in products may be identified and **prioritized** for consideration as being chemicals of concern; and (2) a process by which chemicals of concern in products and their potential alternatives are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. The chemical identification and prioritization process shall include the following factors—volume in state commerce, the **potential for exposure** in a consumer product, and the **potential effects** on sensitive subpopulations. It shall reference and use to the maximum extent feasible, but not be **limited to using only**, the available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes.

There are three very important points I would like to make from this bill—first, the required processes build upon, rather than copy, the concepts and requirements and defined by other government entities. It is my opinion that if the legislative intent were merely to implement the existing chemical regulations from the EU, other countries, or states, then the most expedient way to do so would have been to cite those existing laws. Instead, the authors of this bill chose to move forward the principles of green chemistry through a mandate to the department to

determine how best to limit exposures to and/or reduce the level of hazard from chemicals of concern in consumer products.

I believe, based on the observable impacts on public health and the environment from the use of chemicals today, that current regulatory requirements and methods are not sufficient to adequately control the unnecessary releases of and exposures to all potentially harmful chemicals over the life cycle of consumer products. I, therefore, firmly support the goals of AB 1879 and the intent (if not all of the details) of the new proposed safer consumer products regulations, including establishing lower regulatory thresholds where appropriate, to protect occupational and public health from the use of chemicals of concern in consumer products.

The second point I would like to make is that the bill clearly requires the identification and **prioritization** of chemicals of concern. I believe that one of the biggest weaknesses of the proposed regulations is skipping the very important step of prioritizing the chemicals of concern before going directly to prioritizing products. Similar chemical prioritization processes by other nations (EU, Canada) and governments (state laws for the protection of children from chemicals of concern) have identified a shorter list of priority chemicals based on the severity of known hazards. This enables them to start with the highest concerns, solicit information from manufactures about the products that use these chemicals, and evaluate the potential releases, critical exposure pathways, and potential risks in a systematic manner before listing priority products for immediate evaluation. I believe that adding a process for prioritizing chemicals will refocus the regulations on **chemicals of concern** in priority products and enable much better selection of priority products to evaluate in the next few months and years.

And the third point is the identification and prioritization of chemicals shall, by law, consider potential exposures and effects, not proven exposures and effects. There has been a shift in the development of the regulations that has moved towards proven rather than potential harm. I think this is a very important distinction—knowledge and understanding of chemical hazard traits and behavior should be sufficient warning to list and prioritize the chemicals of concern for consideration and to develop response measures to protect human health and the environment.

***Chemicals of concern list:*** The chemicals of concern are derived from a list of lists—chemicals with specific hazard traits and toxicological endpoints listed by authoritative bodies. This is a great place to start, if not a comprehensive list of all the important lists of known hazard traits. Chemicals that cause sensitization should be part of the list.

There is much overlap between these lists but all of these chemicals are known to be potentially harmful. The factors listed for adding chemicals to the list of chemicals of concern are also good; however, I do not believe that the Department should consider the availability of a safer alternative in determining whether to list a chemical as a chemical of concern. Other mitigation measures and responses may be necessary and appropriate in cases where there are no current substitutes available.

**Threshold:** I fully support the concept, included in the informal draft regulations but eliminated in the proposed regulations, of establishing **by rule** a default AA threshold, of 0.01% by weight (100 ppm) that can be adjusted up or down as appropriate based on the potential adverse impacts of a specific chemical. This is solid concept and a reasonable, if not proven, default value. This value is consistent with the more stringent substance restriction we see for cadmium in many RoHS countries, with the concentration ranges we calculate from Proposition 65 safe harbor levels, and is about the middle of the range we typically see for children's product restrictions. I believe there is precedent in international regulations for establishing a default value that is generally protective for the intended purpose of the rule without demonstrating that the selected value is the most appropriate value for every chemical in every situation.

However, I think it important to note that any adjustment up or down of the rule default should be based on a solid assessment of the available data on the potential risk to humans and the environment. In other words, the burden of proof should move to the department when making technical adjustments to the default threshold outside of the rulemaking process.

Likewise, a very specific chemical of concern—priority product pairing threshold identified outside the open rulemaking process would need to be based on sufficient information to indicate a real potential for adverse impacts above the proposed threshold level. In my opinion, this means the department would need to conduct a chemical-specific priority product risk evaluation through an open, public process, with sufficient review times to provide opportunity for stakeholder and public input, review, comment, and debate before finalizing the threshold. While this may actually provide the best method of determining an appropriate level for a specific chemical of concern—priority product pairing where the potential for harm is great enough that the cost of an AA is justified, this will move much of the debate to the front end of the process and my concern is that this debate is likely to substantially bog down the entire AA process and delay the AA process and regulatory responses needed to reduce the hazard and exposures to chemicals of concerns.

And finally on the topic of thresholds, I will briefly comment on what has been touted as a worldwide “harmonization” of a chemical *de minimis* threshold at 0.1% (1000 ppm). Chemical action thresholds, whether for reporting, labeling, or material restrictions, vary widely depending on both the nature of the substances and the purpose of the regulation. There are many, many examples, the clearest of which is reporting for REACH SVHC at 0.1% by weight in articles vs Canada CMP reporting that is based on 100 kg total substance imported or used by a single manufacturer at any concentration in any given product or component. The latter total number can be adjusted up or down.

Bottom line—the AA threshold should be established to accomplish the purpose of this law—to protect public and the environment—a concentration below which there is no need to further consider limiting exposure throughout the product life cycle, regardless of whether the chemical of concern is added as an intentional ingredient or present as a contaminant in the raw or recycled materials, processing agents, intermediates, air, or water used in the manufacturing process.

**Cumulative:** Adverse impacts on public health and the environment are rarely confined solely to exposure to a single chemical. Any assessment of chemicals of concern in a product needs to at least consider the potential cumulative effect of exposure to more than one chemical of concern exhibiting the same hazard trait. While comprehensive risk assessment is more complicated than the simple addition of concentrations of substances with the same hazard trait, there is precedent for this type of evaluation in the EU labeling requirements for chemical mixtures. In the absence of moving towards full comprehensive risk assessment per se, the surrogate of adding together the concentrations of multiple chemicals of concern with the same hazard trait is a reasonable approximation (although it should be noted that additive does not take into account synergistic effects) for determining whether the product meets the AA threshold exemption requirements.

**Demonstration for AA threshold exemption:** The proposed regulation is not clear about what data are required to substantiate the presence or absence and the concentration of chemicals of concern in the priority product when applying for an AA threshold exemption. It is also not clear what happens if the priority product contains other chemicals of concern exhibiting the same hazard trait as those included as the basis of listing the priority product but which are not well known and, therefore, not included in the priority product listing.

I suggest that knowledge of materials and processes are only adequate as substantiation of the presence or absence and concentration of all chemicals of concern as long as the entire manufacturing process is under the direct control of the responsible entity. The more complicated the product and the more distant the suppliers and manufacturers of materials, ingredients, components, and final assembly of manufactured and formulated products, the more analytical data that should be required to fully substantiate that the AA threshold exemption has been met. I believe the department needs not only to place the burden of proof on the responsible entity but also needs to provide in the rule, the minimum requirements for documentation that the threshold exemption has been met. The department should specify appropriate practical quantitation limits for the chemicals and materials, components, or products specified in priority product listing. This provides certainty for the companies claiming an exemption and ensures uniform implementation across an industry sector.

I support the threshold exemption notification process as a necessary step for ensuring the absence of chemicals of concern in a listed priority product and I think that each exemption notification packet should be available on the web in redacted form with sufficient time for technical review and public comment.

**Chemicals of concern in priority products:** Somewhere in the writing and rewriting of this regulation, the written focus of the AA process and regulatory responses seems to have shifted from evaluation of the alternatives to the **chemicals of concern in priority products** to evaluating alternatives to priority products. Although I do not think this is what the rule is meant to imply, the text of the rule needs to be very clear that this is about defining alternatives for safer chemical selection and minimizing the potential releases and exposures for chemicals of concern throughout the life cycle.

***Practical and implementable:***

The factors outlined in the rule for selecting products and the elements that must be considered in conducting an AA are a reasonable starting point but the actual process for achieving these endpoints is either not laid out well or it is very muddled. Telling us what you want done (chemicals and products) and what outcome needs to be achieved are far better than getting into a regulatory driven but piecemeal process just for the sake of process. My growing fear is that with each later iteration of the rule, the more you specify and the more you drive towards a cookie cutter approach, the less you will actually achieve in real outcomes.

I am sorry but I do not believe that a whole bunch (i.e., 10 chemical-component pairings on a durable product in three years) of piecemeal product AAs are efficient or effective, let alone implementable. My belief is that for the most part, one AA per product per five-year period that considers multiple chemicals of concern of, when appropriate, more than one hazard trait and more than one component would be a more reasonable approach. The obvious exception to this rule of thumb would be to conduct single component AAs for widespread use of relatively standard components that are used in many types of products (e.g., power cords).

By contrast to the piecemeal approach, I would offer the example of RoHS legislation. RoHS required manufacturers to look at the entire product use of specified substances and determine where there were viable alternatives and where viable alternatives were going to take a substantial amount of time to develop (exemptions). This was a lengthy process that required the knowledge and expertise not only of the manufacturers of products but of the whole supply chain that served the electrical and electronic product industry. I believe the RoHS approach is more similar to the discussions I have heard on implementing green chemistry principles—start with the assay of a product and define the scope of the green chemistry challenge and begin there—than it is to relying on randomly picking and choosing chemicals in certain components of a product. Although pieces are important, the application of green chemistry principles is about the whole. This feels like we have lost the holistic approach between last fall and this newer set of proposed regulations.

The obvious question is—does the department really have the knowledge and expertise on product design, materials, and components of every consumer product that may contain chemicals of concern that they feel comfortable with picking and choosing chemicals of concern in materials and components rather than asking the manufacturers take a systematic look at the product and propose an AA plan that describes how to achieve the best outcome for the resources expended?

***Processes and assessors:*** The department has been pushed time and again to more clearly define processes under the guise of promoting certainty for responsible entities that the notifications and reports they produce will meet the requirements. I believe certainty in the AA process comes from achieving and clearly demonstrating the desired outcomes, not from checking the boxes in a meaningless process or blindly applying models, scoring, and checklists. Analytical tools are just that, they provide data for comparison and analysis but not implementable alternatives or definitive answers.

I would contend that the AA team must have a clear understanding of product design, function, materials, product construction and manufacturing processes. These product experts must be closely coupled with environmental experts who can analyze the alternatives within the context of the principles of chemical behavior, release and transport, exposure assessment, toxicology, and life cycle environmental impact analyses.

“Those that lack knowledge and understanding frequently attempt to substitute hard process for creative thinking and expert judgment, with little regard for whether or not that process can actually achieve the desired outcome.”

This law and regulation requires a complicated scientific exercise, focused directly on achieving a very important outcome—protecting public health and the environment by determining the best way to limit exposure to and reduce the hazard posed by chemicals of concern. The AAs and regulatory responses produced under these rules will only achieve the desired outcome through the application of good science, innovative thinking, and the use of expert judgment. None of the outcomes will be enhanced from the development of elaborately laid out processes or the certification of assessors. Understanding the principles, factors, and criteria for consideration specified by the department and weaving them into the identification and analysis of alternative chemicals and actions that can be fully assessed is a better path. In other words, with an endpoint in mind, the technical experts can use their knowledge and experience to most efficiently and effectively achieve the goal.

An open process, systematic technical peer review, and encouraging public participation and comment are imperative to maintaining a level playing field across industry and ensuring quality analyses.

***Trade secrets and disclosure:*** I believe that the entire AA process needs to be as open and transparent as possible but without divulging truly competitive trade secret information. Full disclosure is a desirable endpoint; unfortunately, it is not yet a likely outcome. I think this is a situation where the carrot is likely to work better than a hammer—perhaps some kind of an incentive system that encourages full disclosure of chemicals of concern but I am not quite sure how such a system could be implemented. I would love to see the department think about an incentive for disclosure before the next revisions to the rule.

Thank you for listening.

Best regards,

Marjorie MartzEmerson

## GCREgs@DTSC

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**From:** Cameron McKinley <cammckinley@mac.com>  
**Sent:** Monday, October 01, 2012 9:23 AM  
**To:** GCREgs@DTSC  
**Subject:** Protect consumers from dangerous chemicals

**Categories:** Comment

Dear Dept. of Toxic Substances Control,

PLEASE finish writing regulations to protect citizens from harmful toxic chemicals, and then enact those regulations. Please do it for your own health, your family's health, my family's health and the health of everyone.

Cameron McKinley  


## GCREgs@DTSC

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**From:** sun goddess... <shetaz711@yahoo.com>  
**Sent:** Tuesday, October 09, 2012 10:58 AM  
**To:** GCREgs@DTSC  
**Subject:** COC

**Categories:** Comment

Ms. Von Burg:

Why are you trying to adopt a new legislation about Chemicals of Concern when we (small businesses) haven't even seen a list of the chemicals you want on that list? Isn't that unfair to us? Living in California all my life, I now feel like this state has become run under a dictatorship. It's very sad what California is now turning into and many people are looking to move out and take their business with them.

I'm trying to open a very small business of my own making soap and bath products. I use a glycerin base for my melt and pour that I buy from another company. I don't make this soap, it's easier to buy a 25 lb block and use as needed. I also make cold process which is used with oils (palm, coconut, olive, avocado, canola) and lye. This soap is required to 'rest' for 4-6 weeks to cure. I use it myself and have never had a problem. Lotion, bath salts/scrubs, sugar scrubs and bath bombs:

Lotion is bought as a base product and fragrance is added.

Salt is a dead sea salt and fragrance is added.

Sugar is a raw sugar that is bought in a grocery store with oil (sunflower) and fragrance added.

Bath Bomb is a combination of citric acid and baking soda, small amount of fragrance and color added.

I've never bought a product for my soaps/bath products that have ever had a 'caution' sign by the name saying it could cause cancer or could potentially be dangerous to the public. That's not what I want.

Can you please send a list of what you consider COC in soap products? If you determine lye is one of those chemicals, you will be shutting down every person who makes soap. Lye is a critical ingredient since the discovery of soap from our ancestors.

Thank you,

Robyn McMullin

## GCREgs@DTSC

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**From:** roger mendelson <rbmendel@aol.com>  
**Sent:** Thursday, October 11, 2012 7:56 AM  
**To:** GCREgs@DTSC  
**Cc:** LONI LONI HANCOCK; Gov@govmail.ca.gov  
**Subject:** control and exclude CHEMICALs OF CONCERN

to State Dept of Toxic Substance Control

we're all very worried about toxins in the environment--especially for kids and grandkids. Specifically BPA, Lead, phthalates, and many others.

Stand up to the chemical lobbies and protect people in California and USA.

We're watching you.

Roger Mendelson  
Monique Mendelson  
Adam Mendelson  
Laura Mendelson Stritzel





October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the Metal Finishing Association of Northern California [MFANC], the Metal Finishing Association of San Diego [MFASD], and the Metal Finishing Association of Southern California [MFASC], I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

MFANC, MFASD, and MFASC are nonprofit trade associations of management executives in the fields of metal finishing, electroplating, powder coatings, solar cell manufacturing, anodizing, polishing, decorative plating on plastics, optical coatings and related processes. These are essential components of California's high-tech industries, supplying surface treatments for electronics, aerospace and consumer goods.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

However, we remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

The most concerning aspect of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is

compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on exposure and hazard, and it must avoid duplication and conflicting regulatory requirements.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, the department predicts a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports this two-step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

We appreciate your consideration of our concerns. For further information or questions, please contact me at (310) 901-7745. Thank you.

Sincerely,

*Dan Cunningham*

Dan Cunningham,  
MFANC, MFASC, and MFASD Executive Director  
PO Box 6547  
Burbank CA 91510-6547

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor

## GCREgs@DTSC

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**From:** Amy Meyer <a7w2m@earthlink.net>  
**Sent:** Monday, October 01, 2012 1:29 PM  
**To:** GCREgs@DTSC  
**Subject:** chemicals in consumer products

Please require the state to do what the SF Chronicle called for this morning: **make a list of "chemicals of concern," identify possible alternatives, and regulate the substances to reduce or eliminate public exposure to them.** Everyone will benefit, including the head-in-the-sand sales force of the chemical industry.

Amy Meyer  


**From:** Richard Mezzavilla [<mailto:mez@astound.net>]  
**Sent:** Monday, October 01, 2012 5:23 PM  
**To:** Algazi, Andre@DTSC  
**Subject:** chemicals of concern

Dear Mr. Algazi,

It is my understanding that it will be the task of your department to finish writing the regulations having to do with substances that are on the list of "chemicals of concern" and that after having done so, the department will enact them.

It goes without saying that the health of all Californians is at stake in this matter. I sincerely hope that our state officials have not succumbed to the hordes of lobbyists that have been unleashed on them by the chemical industry.

I urge you and your department colleagues to write the most strident set of regulations that you can. The yet to be born citizens of our great state will someday join with us, the living, in offering all of you our deepest thanks in the future.

Sincerely yours,  
Richard A. Mezzavilla  
Walnut Creek, CA

## GCREgs@DTSC

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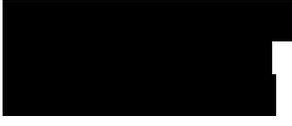
**From:** njmichelli <njmichelli@att.net>  
**Sent:** Monday, August 20, 2012 12:01 PM  
**To:** Von Burg, Krysia@DTSC  
**Subject:** RE: Safer Consumer Product Rulemaking

Hi Krysia,

Thank you. I appreciate your prompt response. I'm trying to sort through how the "trade secret" part of the proposal will work. But it's still a bit confusing for me. Is there anyone that I could contact for clarification on that?

Thank you again,

Nancy Michelli  


Email: [njmichelli@att.net](mailto:njmichelli@att.net)  


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**From:** Von Burg, Krysia@DTSC [<mailto:Krysia.VonBurg@dtsc.ca.gov>]  
**Sent:** Monday, August 20, 2012 11:31 AM  
**To:** [njmichelli@att.net](mailto:njmichelli@att.net)  
**Subject:** Safer Consumer Product Rulemaking

Hi Nancy,

Thanks for the voicemail. If you would like your comment to be considered for the Safer Consumer Product proposed regulations which were published in July 2012, then you will need to submit a new comment.

Please see the following link for all regulatory documents:

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm> or <http://www.dtsc.ca.gov/SCPRegulations.cfm>

Thanks,

*Krysia Von Burg*

Office of Policy

Department of Toxic Substances Control

Tel: (916) 324-2810

[krysia.vonburg@dtsc.ca.gov](mailto:krysia.vonburg@dtsc.ca.gov)

## GCREgs@DTSC

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**From:** Adit Mikaily <aditmikaily@hotmail.com>  
**Sent:** Wednesday, October 10, 2012 12:23 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative - Proposed Regulations

Dear Green Chemistry Regs DTSC,

I wish to express my viewpoint on the proposed Green Chemistry Regulations. As far as your "green" initiative is concerned, I am convinced that the only thing "green" about your initiative is the money that you foresee and anticipate going into your pocket!

Sincerely,

Adit Mikaily  


## GCREgs@DTSC

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**From:** Montgomery, John D <monty@te.com>  
**Sent:** Tuesday, August 07, 2012 5:55 AM  
**To:** GCREgs@DTSC  
**Subject:** Safer Consumer Products Regulations

**Categories:** Question

Where might one find the list of the 1200+ substances that California will focus on with the SCP Reg's.....?

**John D. Montgomery**

**Monty**

Manager - Product Environmental Compliance

  
[monty@TE.com](mailto:monty@TE.com)

## GCREgs@DTSC

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**From:** Montgomery, John D <monty@te.com>  
**Sent:** Thursday, August 09, 2012 1:58 PM  
**To:** GCREgs@DTSC  
**Subject:** RE: Safer Consumer Products Regulations  
**Attachments:** COC-lists-weblinks2[1].pdf

So if I researched each of the websites on your Proposed Chemicals Lists document, I would come up with the 1200 substances?  
(re.: attachment)

Monty

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**From:** GCREgs@DTSC [<mailto:GCREgs@dtsc.ca.gov>]  
**Sent:** Thursday, August 09, 2012 3:57 PM  
**To:** Montgomery, John D  
**Subject:** RE: Safer Consumer Products Regulations

Hi John,

Please see our website as we have posted information regarding the List of Chemicals of Concern,  
<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/SCPA.cfm>

Kind Regards,

Office of Policy  
DTSC

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**From:** Montgomery, John D [<mailto:monty@te.com>]  
**Sent:** Tuesday, August 07, 2012 5:55 AM  
**To:** GCREgs@DTSC  
**Subject:** Safer Consumer Products Regulations

Where might one find the list of the 1200+ substances that California will focus on with the SCP Reg's.....?

**John D. Montgomery**  
**Monty**

Manager - Product Environmental Compliance  
(717) 986-3139 tel  
(717) 877-1799 mobile  
(717) 986-7042 fax  
[monty@TE.com](mailto:monty@TE.com)

**Marcella Moran**

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**From:** Marcella Moran <marcella@alohasantacruz.com>  
**Sent:** Wednesday, September 19, 2012 11:36 AM  
**To:** 'green.chemistry@dtsoc.ca.gov'  
**Subject:** Green Chemistry Concern

*This email address  
does not work.*

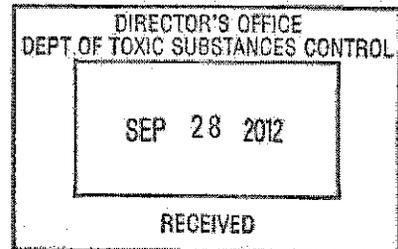
Hello,

My family runs and operates a small retail business in California. I recently attended a large resort tradeshow in Las Vegas where I typically begin to place orders for our upcoming Spring and Summer Seasons. Not a single vendor that I spoke to at this trade show had heard about "Green Chemistry" or the proposed changes. Many of the companies are based out of California. It leaves me feeling very uneasy. If the vendors are unaware of the law changes that may soon take place how can I as a retailer be confident that the merchandise I am buying will be compliant? What has been done to spread the word of the changes to Importers and vendors. If I cannot confidently purchase safe merchandise how can I operate my business and be compliant with the law? I do not think that small business such as our should be held liable for merchandise that is not compliant with these laws. It is not economically feasible for me to test products. I do not want to carry products that are not safe but I cannot economically or efficiently get the information I need to make that determination. The vendor should be required to know whether or not their product is compliant before they are selling it. If the vendor has a product that is suddenly not compliant the retailer should not have to suddenly shoulder that loss. If I have to buy merchandise now to operate my business and in 6 months if it is deemed unsafe what do I do? I cannot afford to shoulder that kind of loss but I also can't afford to not have merchandise for our stores.

1. Please consider providing better communication about these proposed changes to small business and vendors.
2. Please consider the crushing impact this law could potentially have on small retailers. Disney and Walmart sized corporations can afford lawyers and teams of staff to analyze product safety. The average small business cannot and has to rely on the vendor's word.
3. If a product is deemed unsafe please provide the retailer with time to move through the product or if they are not allowed to sell the product provide retailer's with a form of recourse against the vendor (for example the right to return unsafe product).
4. Small retailers should not be held liable for carrying unsafe products unless it can be shown that the product was deemed unsafe and they knew the product was unsafe at the time of ordering.

Thank you for reading my concerns.

Marcella Moran



All visitors are required to sign in prior to attending any meeting at the Visitor and Environmental Services Center, located just inside and to the left of the building's public entrance. Please allow adequate time to sign in and receive a visitor badge before the public hearing begins.

**Notice to Hearing Impaired - Accessibility.** If you have special accommodation or language needs, please contact Reasonable Accommodation Coordinator Adrian Recio, at (916) 324-3095 or by e-mail at [ARecio@dtsc.ca.gov](mailto:ARecio@dtsc.ca.gov) as soon as you read this document. TTY/TDD/Speech-to-Speech users may dial 7-1-1 for the California Relay Service.

## AUTHORITY AND REFERENCE

### Authority

These regulations are being adopted under the following authorities:

Health and Safety Code section 25252: This section authorizes and requires the Department of Toxic Substances Control (DTSC) to adopt regulations to establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern. This section directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. This section also directs DTSC to reference and use available information from various sources, but does not limit DTSC to referencing and using only this information.

Health and Safety Code section 25253: This section authorizes and requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that take into consideration, at a minimum, thirteen (13) specified factors. This section also requires that the regulations specify the range of regulatory responses that DTSC may make following the completion of an alternatives analysis, including, but not limited to, eight (8) specified responses and "any other outcome the department [DTSC] determines accomplishes the purposes of [article 14 of the statutes]".

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991.) This section grants DTSC authority to adopt regulations to execute its duties.

### Reference

These regulations implement, interpret, or make specific the following statutes:

Health and Safety Code sections 25251, 25252, 25253, 25257, and 25257.1.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

### **Policy Statement Overview**

#### Background

There are currently more than 80,000 chemicals approved under federal law for use in the United States (U.S.). Each day, a total of 42 billion pounds of chemical substances are produced or imported in the U.S. for commercial and industrial uses. An additional 1,000 new chemicals are introduced into commerce each year.

Approximately one new chemical comes to market every 2.6 seconds, and global chemical production is projected to double every 25 years. The average U.S. consumer today comes into contact with 100 chemicals per day. In 2009, the U.S. Centers for Disease Control and Prevention released the Fourth National Report on Human Exposure to Environmental Chemicals, which measured 212 chemicals in the blood and urine of a representative population of the United States. The 2009 Report was updated in February, 2012 to include updated tables for 66 chemicals and tables for 34 new chemicals. California consumers and businesses are becoming increasingly aware and concerned about the abundance of chemicals that they are exposed to in the products that they use on a day-to-day basis in their homes and in the workplace.

For more than a decade, the California Legislature has considered nearly a hundred bills proposing chemical bans and broader chemical policies for California, heard testimony from "battling scientists" and was interested in developing a broader, more comprehensive approach to chemicals policy.

In 2003, the Senate Environmental Quality Committee and the Assembly Committee on Environmental Safety and Toxic Materials commissioned a report from the University of California (U.C.) to investigate the current legal and regulatory structure for chemical substances and to report on how a California chemicals policy could address environmental and health concerns about chemical toxicity, build a long-term capacity to improve the design and use of chemicals, and understand the implications of European policy on the California chemical market.

In 2006, authors from U.C. Berkeley presented the commissioned report, *Green Chemistry in California: A Framework for Leadership in Chemicals Policy and Innovation* and made a connection between weaknesses in federal policy, namely the Toxic Substances Control Act (TSCA), and the health and environmental damage happening in California. The report broadly summarized their findings into what they called the "three gaps":

- *Data Gap*: There is a lack of information on which chemicals are safe and which are toxic, and what chemicals are in products. The lack of access to chemical data creates an unequal marketplace. California businesses cannot choose and make safer products and respond to consumer demand without ingredient disclosure and safety testing.
- *Safety Gap*: Government agencies do not have the legal tools or information to prioritize chemical hazards. Under TSCA, only 5 chemicals out of 83,000 have been banned since 1976. The California Legislature has frequently addressed this problem by approving individual chemical bans. Chemical bans come before the Legislature because there are very few other mechanisms in place at the federal or State level that can remove harmful chemicals from the marketplace.
- *Technology Gap*: There is an absence of regulatory incentive and market motivation which stems from the data gap, and a lack of educational emphasis on green chemistry methodologies and technologies. In order to build a substantial green chemistry infrastructure, a coincident investment and commitment must be made to strengthen industrial and academic research and development.

In 2007, the California Environmental Protection Agency launched *California's Green Chemistry Initiative* within DTSC. The *California Green Chemistry Initiative Final Report* released in December 2008 included the following six policy recommendations for implementing this comprehensive program in order to foster a new era in the design of a new consumer products economy, which includes inventing, manufacturing and using toxic-free, sustainable products.

1. Expand Pollution Prevention and product stewardship programs to more business sectors to focus on prevention rather than simple source reduction or waste controls.

2. Develop Green Chemistry Workforce Education and Training, Research and Development and Technology Transfer through new and existing educational program and public/private partnerships.
3. Create an Online Product Ingredient Network to disclose chemical ingredients for products sold in California, while protecting trade secrets.
4. Create an Online Toxics Clearinghouse, an online database providing data on chemical, toxicity and hazard traits to the market place and public.
5. Accelerate the Quest for Safer Products, creating a systematic, science-based process to evaluate chemicals of concern and identify safer alternatives to ensure product safety.
6. Move Toward a Cradle-to-Cradle Economy to leverage market forces to produce products that are "benign-by-design", in part, by establishing a California Green Products Registry to develop green metrics and tools for a range of consumer products and encourage their use by businesses.

In 2008, Assembly Bill 1879 (Chapter 559, Feuer) and Senate Bill 509 (Chapter 560, Simitian), were signed into law by Governor Schwarzenegger to implement two key recommendations of the *California Green Chemistry Initiative Final Report*: acceleration of the quest for safer products, and creation of an online toxics clearinghouse - recommendations #4 and #5 above.

### Broad Objectives

The proposed regulations that are the subject of this notice, and the authorizing statutes (Health and Safety Code sections 25252 and 25253), are intended to implement recommendation #5 of the *California Green Chemistry Initiative Final Report* - Accelerate the Quest for Safer Products, and, thus, create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.

### Specific Objectives

The specific objectives of the proposed regulations are to:

- Establish a process to identify and prioritize those chemicals or chemical ingredients in consumer products that may be considered as being a chemical of concern.
- Establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by chemicals of concern.
- Specify the range of regulatory responses that DTSC may take following the completion of the alternatives analysis.

### Proposed Regulations

The proposed regulations would add a new chapter 55, Safer Consumer Products, to division 4.5 of Title 22, California Code of Regulations. These regulations are necessary to satisfy the mandates of Health and Safety Code sections 25252 and 25253, which require DTSC to adopt regulations to establish a process to identify and evaluate chemicals of concern in consumer products and identify safer alternatives, and to specify regulatory responses that may be imposed upon completion of the alternatives analysis process.

### Benefits

The proposed regulations are among the first comprehensive, state-level efforts to find safer alternatives to hazardous chemicals and are viewed as a potential national model for chemicals policy reform. The rulemaking is a preemptive strategy that reduces the use of toxic substances in the design of products and industrial processes with the aim of creating safer and sustainable products that do not threaten human health or persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water and a safer workplace. The rulemaking also promotes transparency by compelling chemical manufacturers to provide sufficient information for businesses, consumers and public agencies to choose viable safer alternatives to hazardous chemicals used in consumer products.

### Relation to Existing State Regulations

The proposed regulation is not inconsistent or incompatible with any existing state regulations. An automated search of Titles 19 and 22 using the following keywords: "consumer products", "chemicals in consumer products", and "chemicals in commerce", was conducted via Westlaw and yielded no conflicting state regulations. In addition, DTSC worked with the Office of Environmental Health Hazard Assessment (OEHHA), the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies.

### I. Summary of Regulations

#### **A. Four-Step Process** [Section 69501(a)]

The regulations provide for a four-step continuous, science-based, iterative process to identify safer consumer product alternatives:

- DTSC - The regulations establish an immediate list of Chemicals of Concern (~1,200) based on the work already done by other authoritative organizations, and specify a process for DTSC to identify additional chemicals as Chemicals of Concern (COCs).\* [Article 2, see section II for further details.]
- DTSC - The regulations require DTSC to evaluate and prioritize product/COC combinations to develop a list of "Priority Products" for which an alternatives analysis must be conducted. [Article 3, see section II for further details.]
- Product Manufacturers - The regulations require responsible entities (manufacturers, importers, and retailers) to notify DTSC when their product is listed as a Priority Product. DTSC will post this information on its website. Manufacturers (or other responsible entities) for a product listed as a Priority Product must perform an alternatives analysis (AA) for the product and the Chemicals of Concern in the product to determine how best to limit exposures to, or the level of adverse public health and environmental impacts posed by, the Chemicals of Concern in the product. [Article 5, see section III for further details.]
- DTSC - The regulations require DTSC to identify and impose regulatory responses to effectively prevent or limit adverse public health and/or environmental impacts, if any, posed by the Priority Product/Chemical of Concern (if the manufacturer decides to retain the Priority Product), or the adverse impacts posed by the alternative chemical/product selected to replace the Priority Product. [Article 6, see section IV for further details.]

#### **B. Applicability** [Section 69501(b)]

Except as noted below, the regulations apply to all consumer products that contain a Chemical of Concern, and are sold, offered for sale, distributed, supplied, or manufactured in California. The regulations do not apply to the following products:

(1) Products exempted by law (Health and Safety Code section 25251): dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials, and medical devices; food; and pesticides. The regulations also do not apply to products used solely to manufacture a product exempted by law.

(2) Products manufactured or stored in, or transported through, California solely for use out-of-state.

### **C. Responsibility for Compliance**

(1) The regulations [Section 69501.1(a)(54)] define "responsible entity" to include:

(i) The manufacturer (i.e., the person that makes the product or the person who controls the specifications and design of, or use of materials in, the product).

(ii) The US importer of the product.

(iii) Retailers who sell the product in California.

However, the principal duty to comply with the requirements of the regulations that apply to responsible entities lies with the manufacturer. If the manufacturer does not comply, the importer, if any, then has a duty to comply. A retailer is required to comply with the regulations only if the manufacturer and importer(s) (if any) fail to comply, and only after this information is posted on the Failure to Comply List on DTSC's website. [Section 69501.2(a)(1)]

(2) The regulations [Section 69501.2(a)] require a responsible entity for a product to ensure compliance with the requirements pertaining to:

(i) Notifying DTSC that its product is a Priority Product [Section 69503.7], or alternatively submitting an Alternatives Analysis Threshold Exemption Notification [Sections 69503.5 and 69503.6] or a Chemical of Concern Removal Notification [Section 69505.1(g)];

(ii) Performing an AA, and submitting AA Reports to DTSC, for its product; and

(iii) Complying with regulatory responses applicable to its product.

(3) A manufacturer or importer may opt out of complying with the above requirements by demonstrating to DTSC that the product is no longer being sold, offered for sale, distributed, supplied, or manufactured in California. [Section 69501.2 (b)]

A retailer who becomes responsible for complying with the above requirements, due to non-compliance by the manufacturer/importer, may opt out by ceasing to order the product and providing a notification to DTSC. [Section 69501.2 (c)]

If the manufacturer or importer subsequently introduces into the California marketplace a product that replaces (in terms of use and customer bases) the removed Priority Product, and that replacement product contains a Chemical of Concern, the manufacturer or importer must provide a notice to DTSC. [Section 69501.2 (b)]

(4) The regulatory requirements applicable to responsible entities may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, one or more responsible entity(ies). (This does not apply to the Priority Product Notification or Alternatives Analysis Threshold Exemption Notification requirements.) [*Section 69501.2(a)(2)*]

#### **D. Consequences of Non-Compliance**

(1) When DTSC determines a requirement has not been fulfilled for a product, DTSC will issue a notice of non-compliance to the manufacturer and importer(s). [*Section 69501.2(d)*]

(2) If the non-compliance is not remedied, the product and information concerning the product will be placed on a Failure to Comply List maintained on DTSC's website. The regulations specify the conditions under which a product will be removed from the Failure to Comply List. [*Section 69501.2(d)*]

(3) DTSC may conduct audits to determine compliance with the requirements of the regulations pertaining to alternatives analyses, regulatory responses, and various notifications and information submittals. [*Article 9, Section 69509*]

(4) In accordance with *article 8 of chapter 6.5 of division 20 of the Health and Safety Code*, DTSC may also initiate enforcement actions, including imposition of fines and penalties, against responsible entities for failure to comply with the regulations.

#### **E. Chemical and Product Information** [*Section 69501.4*]

DTSC's implementation of the regulations will be informed by a wealth of information that DTSC will obtain from the public domain. In addition, DTSC will request information from responsible entities for products and chemical manufacturers/importers. DTSC will maintain on its website a Response Status List that provides information as to how a responsible entity or a chemical manufacturer/importer has or has not responded to a request for information from DTSC. DTSC will also maintain on its website a Safer Consumer Products Partner Recognition List that identifies persons that have voluntarily provided DTSC with information that advances the quest for safer consumer products.

#### **F. Information on DTSC's Website** [*Section 69501.5*]

The regulations require DTSC to post on its website a comprehensive list of information pertaining to implementation of the regulations. In some cases, a notice of the availability of the information will be provided to persons on DTSC's electronic mailing list for these regulations. This will be DTSC's main avenue of communication with responsible entities and the public.

#### **G. Disputes** [*Article 7, commencing with Section 69507*]

The regulations provide a process for a responsible entity to dispute an action taken by DTSC. A requirement imposed on the responsible entity by DTSC, and posting of information in the Failure to Comply list concerning the non-compliance with that requirement, will be stayed while a dispute is pending. (The dispute process does not apply to: actions taken by DTSC with regard to the listing of Chemicals of Concern, petitions concerning the chemicals and products lists, and trade secret protection claims.)

#### **H. Certified Assessors** [*Article 8, commencing with Section 69508*]

Beginning two years after the regulations become effective, an AA must be conducted by or under the responsible charge of one or more persons certified as an assessor by a DTSC-designated accreditation body, as

well as meeting specified education and experience requirements. The regulations spell out the requirements for certified assessors and accreditation bodies.

## **I. Trade Secret Protection** *[Article 10, commencing with Section 69510]*

The regulations set out provisions for: submitting trade secret claims and the treatment of information submitted under the regulations for which a claim of trade secret protection is asserted by the submitter. The regulations are based on the authorities for handling trade secrets found in Health and Safety Code section 25257, the Uniform Trade Secrets Act (See Civil Code Section 3426.1), and the Public Records Act (See Government Code Section 6254.7).

## **II. Chemical and Product Prioritization**

### **A. Chemicals of Concern (COC) Identification**

(1) Initial List of COCs - As of the effective date of the regulations, ~1,200 chemicals are identified as COCs because they exhibit a hazard trait or an environmental or toxicological endpoint (listed in OEHHA's regulations), and are listed or identified by one or more authoritative bodies specified in the regulations. *[Section 69502.2(a)]* NOTE: ~500 additional chemicals currently used only in pesticides and drugs (and, thus, excluded from these regulations under Health and Safety Code section 25251) could be added to the list in the future if they are used in products that are not excluded under Health and Safety Code section 25251.

(2) Additions to the Initial List of COCs - DTSC may identify additional chemicals (that exhibit a hazard trait or an environmental or toxicological endpoint) as COCs based on consideration of the following factors *[Section 69502.2(b)]*:

- Chemical adverse public health and environmental impacts
- Adverse impacts of special consideration - Adverse impact(s) for:
  - (i) Sensitive subpopulations;
  - (ii) Environmentally sensitive habitats;
  - (iii) Endangered and threatened species;
  - (iv) Environments in California designated as impaired; and
  - (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.
- Exposures to the chemical
- Availability of substantiating reliable information
- Availability of safer, functionally acceptable, alternative chemicals

Refer to the definitions in the regulations *[Section 69501.1]* for the list of adverse public health and environmental impacts, physicochemical properties, and environmental fate properties that will be considered during the identification of COCs and the prioritization of COCs/products.

(3) Listing Process - An informational list of those chemicals identified as COCs as of the effective date of the regulations will be posted on DTSC's website within 30 days after the regulations become effective. Any subsequent revisions to the list will be made in accordance with the listing process described in II.D. below. [Section 69502.3]

## **B. Chemicals of Concern and Product Prioritization**

(1) Product Prioritization Criteria [Section 69503.2(a)]: DTSC will evaluate products to determine the adverse impacts for, and exposures associated with the product, to the COCs in each product based on consideration of the factors listed below. Based on this evaluation, DTSC may list as Priority Products those products that are determined to be of high priority.

(a) Adverse Impacts and Exposures [Section 69503.2(a)(1)]: The adverse public health and environmental impacts posed by the COC(s) in the product due to exposures during the manufacture, useful life, and end-of-life disposal or management of the product, considering:

- Adverse Impacts from the COCs - The ability of the COC(s) in the product to contribute to or cause adverse public health and/or environmental impacts, considering specified factors. This includes consideration of adverse impact(s) for:

- (i) Sensitive subpopulations;

- (ii) Environmentally sensitive habitats;

- (iii) Endangered and threatened species;

- (iv) Environments in California designated as impaired; and

- (v) Adverse impacts associated with the ability of the chemical to contribute to or cause widespread adverse public health and/or environmental impacts.

- Exposures - Public health and/or environmental exposures to the COC(s) in the product, considering:

- (i) Market presence information for the product;

- (ii) Reliable information regarding public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product, and reliable information demonstrating the occurrence of exposures to the COC(s) in the product;

- (iii) Information concerning the household presence and use of the product, and other products containing the same COC(s);

- (iv) Public and/or aquatic, avian, or terrestrial animal or plant organism exposures to the COC(s) in the product during the product's life cycle; and

- (v) Product uses, or discharges or disposals, in any manner that would contribute to or cause adverse waste and end-of-life impacts.

(b) Availability of Information [Section 69503.2(a)(2)]: The availability of information to substantiate the adverse impacts and exposures.

(c) Other Regulatory Programs [Section 69503.2(a)(3)]: The scope of federal and/or other California State laws, and any applicable international trade agreements, under which the product or the COC(s) is/are regulated, and the extent to which these other regulatory requirements address, and provide protections with respect to, the same adverse public health and environmental impacts and exposure pathways that are being considered as a basis for the product being listed as a Priority Product.

(2) Key Prioritization Factors [Section 69503.2(b)]: DTSC will give priority to products meeting both of the following criteria:

- The COCs in the product have a significant ability to contribute to or cause adverse public health and environmental impacts.
- There is a significant ability for the public and/or aquatic, avian, or terrestrial animal or plant organisms to be exposed to the COCs in the product in quantities that would contribute to or cause adverse public health or environmental impacts, which may include consideration of how widely the product is distributed in commerce and how widely the product is used by consumers.

### **C. Process to Evaluate Products [Section 69503.3]**

(1) Adverse Impacts and Exposures and Availability of Information - DTSC will begin the product evaluation and identification process by using available information to evaluate the product's adverse impact and exposure factors, along with the extent of available information.

(2) Other Regulatory Programs - DTSC will then assess whether, and to what extent, any of these adverse impacts and/or exposures pathways are adequately addressed by other California and federal laws, and international agreements. DTSC will adjust the prioritization of the product based on whether listing the product as a Priority Product would meaningfully enhance protection of public health and/or the environment in light of any protections already provided under other laws.

(3) Priority Products - DTSC may list as a Priority Product one or more products determined to be of high priority after completion of the steps (1) and (2) described above.

(4) Safer Alternatives - DTSC may consider whether there is a readily available safer alternative, that is functionally acceptable and technically and economically feasible, to further adjust the prioritization prior to listing a product as a Priority Product.

(5) Key Prioritization Factors - Prior to issuing the proposed and final Priority Products lists, DTSC will evaluate the list for consistency with the key prioritization factors described in B.(2) above, and make adjustments as needed.

(6) Priority Product Work Plan - No later than January 1, 2014, DTSC will issue a Priority Product Work Plan that identifies the product categories that will be evaluated to identify products to be added in the future to the Priority Products list during the next three years. The regulations specify conditions under which DTSC may revise the work plan subsequent to its issuance. Subsequent work plans will be issued no later than one year before the three-year expiration date of the current work plan.

(7) Initial Priority Products List - Prior to January 1, 2016, DTSC will list a product as a Priority Product only if the product is being listed on the basis of one or more COCs in the product meeting specified criteria.

### **D. Listing Process [Sections 69502.4 and 69503.7]**

- (1) Prior to finalizing each augmentation to the initial COCs list, and the initial and revised Priority Products list, DTSC will make the proposed list available for public review and comment for a minimum 45-day period.
- (2) After consideration of public comments on a proposed list, DTSC will finalize and post the final list on its website.
- (3) DTSC will review, and revise as appropriate, the Priority Products list at least once every 3 years.
- (4) The initial proposed list of Priority Products, which will include no more than five products, will be made available for public review and comment no later than 180 days after the effective date of the regulations.
- (5) For some products, DTSC will specify in the Priority Products list the product component, or the homogenous material within a component, that is the required minimum focus of the alternatives analysis for the product.
- (6) Each responsible entity for a product listed on the Priority Products list must provide to DTSC a Priority Product Notification, an Alternatives Analysis Threshold Exemption Notification, Priority Product Removal Notification, or a COC Removal Notification within 60 days after the product is listed as a Priority Product.

#### **E. Petition Process** *[Sections 69504 and 69504.1]*

Subject to one specified exception, any person may petition DTSC to add or remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. High priority will be given to petitions by federal and other California State agencies that relate to the petitioning agency's legislative and/or regulatory authorities. After granting a petition, DTSC will evaluate and, if applicable, prioritize the chemical and/or the product in accordance with the prioritization processes described above.

#### **F. Alternatives Analysis Threshold Exemption**

- (1) A product that is listed as a Priority Product and that meets the criteria for an alternatives analysis exemption will be exempt from the requirement to perform an alternatives analysis, if the responsible entity submits an Alternatives Analysis Threshold Exemption Notification. *[Section 69503.5(a)]*
- (2) An alternatives analysis exemption applies only to products in which the concentration of the COC(s), that are the basis for the product being listed as a Priority Product, does not exceed the applicable alternatives analysis threshold specified by DTSC. *[Section 69503.5(b)]*
- (3) The regulations specify criteria to be used by DTSC when setting the alternatives analysis threshold for each COC in a Priority Product. This includes: (i) the ease or difficulty of removing the COC from the product if the COC is a contaminant rather than an ingredient; (ii) the detection limit for the COC; and (iii) various public health and environmental protection considerations. In no case may DTSC specify an alternatives analysis threshold that is lower than the detection limit for the COC. *[Section 69503.5(c)]*
- (4) If multiple COCs that exhibit the same hazard trait and/or environmental or toxicological endpoint(s) are identified as the basis for the product being listed as a Priority Product, DTSC may specify a single alternatives analysis threshold that applies to the total concentration in the Priority Product of all such COCs. *[Section 69503.5(d)]*

(5) The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification [Section 69503.6(a)]. The responsible entity is required to notify DTSC if the information in the Alternatives Analysis Threshold Exemption Notification significantly changes, or the product no longer meets the criteria for an alternatives analysis exemption [Section 69503.6 (c) and (d)].

### **III. Alternatives Analyses (AAs)**

#### **A. Guidance Materials**

The regulations require DTSC to prepare, and make available on its website, guidance materials to assist persons in performing AAs, and to post on its website AAs that are available in the public domain and are supported by reliable information. [Section 69505]

#### **B Alternatives Analyses - General Requirements**

(1) A responsible entity for a Priority Product must conduct an AA for the Priority Product, and submit a Preliminary AA Report and a Final AA Report to DTSC within specified timeframes. [Section 69505.1(c)]

- The Preliminary AA Report must be submitted no later than 180 days after the date the product is listed on the final Priority Products list, unless DTSC specifies a different due date for the product in the Priority Products list.

- The Final AA Report must be submitted no later than 12 months after the date DTSC issues a notice of compliance for the Preliminary AA Report, unless the responsible entity requests, and DTSC approves, a longer period of time not to exceed 24 months (or up to 36 months if regulatory safety and/or performance testing is required for the alternatives being considered).

(2) The regulations allow for a responsible entity to request a one-time extension, not to exceed 90 days, for submitting the Preliminary and/or Final AA Report, if the extension request is based on circumstances that could not reasonably be anticipated or controlled by the responsible entity. [Section 69505.1(d)]

(3) Each AA completed two years or later after the effective date of the regulations must be performed, and each Preliminary and Final AA Report submitted two years or later after the effective date of the regulations must be prepared, by or under the responsible charge of an assessor certified by an accreditation body designated by DTSC. [Section 69505.1(e)] (See Article 8, commencing with Section 69508, of the regulations for further details concerning assessor requirements and accreditation bodies.)

(4) The regulations allow a responsible entity to fulfill the AA requirements by submitting a report for a previously completed AA for the Priority Product - if DTSC determines that the report is substantially equivalent to the AA Report requirements specified in the regulations, and that the report contains sufficient information to identify regulatory response(s). [Section 69505.1(f)]

(5) If a responsible entity reformulates the Priority Product to remove the COC(s), that is/are the basis for the Priority Product listing, without adding a substitute chemical, the responsible entity may submit a Chemical of Concern Removal Notification to the Department in lieu of conducting an AA and submitting an AA Report. [Section 69505.1(g)]

#### **C. Analysis of Priority Products and Alternatives**

(1) The regulations require that each AA be conducted in two stages. The Preliminary AA Report is submitted to DTSC after completion of the first AA stage, and the Final AA Report is submitted after completion of the second AA stage. [Section 69505.2(a)]

(2) *The first stage of the AA includes:*

(a) Step 1, Identification of Product Requirements and Function of COCs [Section 69505.3(b)(1)]:

- The function, performance, and legal requirements associated with the Priority Product that must be met by alternatives being considered.
- The function of the COC(s) in meeting the Priority Product's function, performance, and legal requirements.
- A determination as to whether the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product's function, performance, and legal requirements.
- If it is determined that neither the COC(s) or substitute chemical(s) is/are necessary to meet the Priority Product requirements, the removal of the COC(s) from the Priority Product without the addition of substitute chemical(s) must be evaluated in the AA as one of the alternatives to the Priority Product.

(b) Step 2, Identification of Alternatives [Section 69505.3(b)(2)]:

Identification of alternatives for consideration that meet the requirements for the Priority Product, and eliminate or reduce the concentration of the COC(s) in the Priority Product and/or reduce or restrict for public health and/or environmental exposures to the COC(s) in the Priority Product. The responsible entity is required to include in the AA consideration of any identified existing viable alternatives.

(c) Step 3, Initial Screening of Alternative Chemicals [Section 69505.3(b)(3)]:

- The responsible entity is required to collect and use available relevant information to identify the adverse public health and environmental impacts associated with each chemical being considered as an alternative to the COC(s) in the Priority Product.
- Using this information, the responsible entity must compare each of the identified alternative chemicals with the COC(s) in the Priority Product.
- The responsible entity must eliminate from further consideration in the AA any alternative chemical that it determines poses equal or greater adverse public health and/or environmental impacts than the COC(s).

(d) Step 4, Consideration of Additional Information [Section 69505.3(b)(4)]:

As part of the first stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above.

(e) Step 5, Identification of Next Steps [Section 69505.3(b)(5)]:

The responsible entity is required to prepare a work plan and proposed implementation schedule for completion of the second AA stage, as described in (3) below, and preparation and submittal of the Final AA Report.

Abridged AA Report [Section 69505.2(b)]:

A responsible entity, that determines (after completion of steps 1 through 4 above) that a functionally acceptable alternative is not available or feasible, may prepare and submit an Abridged AA Report, in lieu of Preliminary and Final AA Reports, if the responsible entity meets specified requirements.

(3) *The second stage of the AA includes:*

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives [*Section 69505.4(a)*]:

• A factor, in conjunction with an associated exposure pathway and life cycle segment, is relevant if:

(i) It makes a demonstrable contribution to the adverse impacts of the Priority Product and/or one or more alternatives under consideration, and

(ii) There is a demonstrable difference in the factor's contribution to such impacts between two or more of the alternatives being considered.

• The responsible entity must use available quantitative information and analysis tools, supplemented by available qualitative information and analysis tools, to identify the factors listed below, and the associated exposure pathways and life cycle segments, that are relevant for the comparison of the Priority Product and the alternatives under consideration:

(i) Multimedia life cycle impacts and Chemical hazards:

- Adverse environmental impacts
- Adverse public health impacts
- Adverse waste and end-of-life impacts
- Environmental fate properties
- Materials and resource consumption impacts
- Physical chemical hazards
- Physicochemical properties

(ii) Product function and performance

(iii) Economic impacts

• The identification of relevant exposure pathways must consider:

(i) Chemical quantity information

(ii) Exposure factors

(b) Step 2, Comparison of the Priority Product and Alternatives [*Section 69505.4(b)*]:

The responsible entity must use available quantitative information and analyses, supplemented by available qualitative information and analyses, to evaluate and compare the Priority Product and each alternative with respect to each relevant factor and associated exposure pathways and life cycle segments.

(c) Step 3, Alternative Selection Decision [*Section 69505.4(c)*]:

The responsible entity selects the alternative that will replace or modify the Priority Product, or decides to retain the Priority Product.

(d) Step 4, Consideration of Additional Information [*Section 69505.4(d)*]:

As part of the second stage of the AA, the responsible entity may also consider other relevant information and data not specifically identified above, including reconsideration of factors evaluated in the first stage of the AA.

(e) Step 5, Identification of Next Steps [*Section 69505.4(e)*]:

The responsible entity is required to prepare a Final AA Report that includes an implementation schedule for implementing the selected alternative, if any, and/or any proposed regulatory responses.

(4) A responsible entity may use an AA process that differs from the process described above if certain requirements are met, including [*Section 69505.2(c)*]:

- The alternate process will provide the information needed to prepare an AA Report that substantially meets the AA Report requirements specified in the regulations.
- The alternate process will compare the Priority Product and the alternatives using the same factors and associated exposure pathways and life cycle segments that would be used if the process specified in the regulations was followed.
- The responsible entity submits a work plan to DTSC for the alternate process no later than 60 days after the product is included on the Priority Products list.

#### **D. Alternatives Analysis Reports**

(1) The Preliminary and Final AA Reports must include the information listed below. All differences in the information and analyses presented in the Preliminary AA Report and the Final AA Report must be identified and explained in the Final AA Report. [*Section 69505.5(a)*]

- An **executive summary** [*Section 69505.5(b)*]. The executive summary cannot include any information for which trade secret protection is claimed - this will enable the executive summary to be posted on DTSC's website in its entirety.
- Information regarding the **preparer** of the AA Report [*Section 69505.5(c)*]
- Information regarding the **responsible entity** and the **supply chain** for the product [*Section 69505.5(d)*]
- Information describing the **Priority Product** and the **COCs** [*Section 69505.5(e)*]
- A description of the **alternatives** chosen to be evaluated and compared, and an explanation of the rationales for selecting and screening out specific alternatives at each stage of the alternatives comparison process. [*Section 69505.5(f)*]

- Detailed information on the **evaluation and comparison of the Priority Product and its alternatives** for all of the relevant comparison factors, and associated exposure pathways and life cycle segments. *[Section 69505.5(f)]*
- Identification of **comparison factors**. The AA Reports must identify which factors, and associated exposure pathways and life cycle segments, were determined to be relevant for evaluation and comparison of the Priority Product and its alternatives. The AA Report must explain the rationales for each factor, exposure pathway, and life cycle segment determined not be relevant. *[Section 69505.5(g)]*
- A description of the **methodology** used to conduct the AA *[Section 69505.5(h)]*
- Identification of all information used as **supporting information** in performance of the AA and preparation of the AA Reports. This information must be made available to DTSC, upon request. The Final AA Report must also identify any **information gaps**. *[Section 69505.5(i)]*
- Identification and description of the **alternative selected** to replace or modify the Priority Product (or a decision to retain the Priority Product); the **implementation plan** for the selected alternative, if any; and any **proposed regulatory responses**. *[Section 69505.5 (j) and (k)]*

(2) The information in the Final AA Report concerning the alternative selection decision must include:

- A description of the alternative, if any, selected, and the rationales for the selection decision. This includes an analysis that evaluates and compares the selected alternative against the Priority Product, and an explanation of the reasons for the selection decision, or, alternatively, for the decision not to select and implement an alternative to the Priority Product, whichever is applicable. *[Section 69505.5(j)(2)]*
- A discussion of the functional and performance acceptability of the selected alternative as compared to the Priority Product. If no alternative is selected, this information must be provided for each alternative considered. *[Section 69505.5(j)(2)(A)]*
- The rationales for selecting an alternative that retains one or more COC(s) or uses substitute chemicals, if it is determined during the AA that neither the COC(s) nor substitute chemicals are necessary to satisfy the requirements for the Priority Product (i.e., functional, performance, and legal requirements). *[Section 69505.5(j)(2)(B)]*
- A list of all chemicals known, based on available information, to be in the selected alternative that differ in type, or are present at a higher concentration, relative to the chemicals contained in the Priority Product; available environmental fate information for the chemicals; available hazard trait and environmental and toxicological endpoint information for those chemicals; and available chemical identification and description information for those chemicals. *[Section 69505.5(j)(2)(C)]*

(3) After the Final AA Report is submitted, if the alternative selection decision specified in the Final AA Report changes prior to introduction of the new product into the California marketplace, the responsible entity is required to submit a revised Final AA Report with an explanation of the change. A revised Final AA Report is also required if the original alternative selection decision was to retain the Priority Product, and the responsible entity later decides to replace the Priority Product with an alternative product. *[Section 69505.2(d)]*

#### **E. DTSC Review and Determinations for AA Reports** *[Section 69505.6]*

(1) Within 60 days of receiving an AA Report, DTSC will review the AA Report for compliance with the regulations, and issue a notice of compliance, a notice of deficiency, or a notice of ongoing review. Notices of

deficiency will generally give the responsible entity 60 days to remedy the deficiency. If the submitter of the AA Report fails to adequately and timely respond to 2 notices of deficiency for the Final AA Report (or 1 notice of deficiency for the Preliminary AA Report), the product will be placed on the Failure to Comply List.

(2) Notices of compliance for Preliminary AA Reports will specify the due date for submitting the Final AA Report, which will range from 12 to 24 months (or up to 36 months if regulatory safety and/or performance testing is required for alternatives being considered) after DTSC issues the notice of compliance. In the notice of compliance for the Final AA Report, or in a separate notice, DTSC will provide notice of its proposed determination as to whether one or more of the regulatory responses that are triggered by a DTSC determination or other action (as described below) are required. The regulatory response determination does not become final until completion of the regulatory response public notice and comment process described below.

#### **IV. Regulatory Responses**

##### **A. Regulatory Response Selection Principles [Section 69506]**

(1) DTSC will require implementation of regulatory responses designed to protect public health and the environment, and maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.

(2) DTSC will give preference to regulatory responses providing the greatest level of inherent protection (i.e., avoidance or reduction of adverse impact or exposure achieved through product or process redesign, rather than through administrative or engineering controls designed to limit exposure to a COC in a product.

(3) In selecting regulatory responses, DTSC may consider any or all of the following factors:

- The likely actual effectiveness of the regulatory response, including the capacity of responsible entities to comply, and the ability of end-users to understand and act upon any information and directions provided with respect to the product;
- The relative cost-effectiveness of the regulatory response as compared to other possible responses;
- The administrative and other burdens that would be placed upon DTSC, the responsible entities, the product end-users, and the public;
- Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations; and
- The ease and efficacy of enforcement of the regulatory response.

##### **B. Applicability**

(1) The regulations specify regulatory responses that will, under specified conditions, apply to [Section 69506.1(a)]:

- Products manufactured as a selected alternative following completion of an AA;
- Priority Products for which an alternative is not selected; and
- Priority Products that will remain in commerce pending development and distribution of the selected alternative.

(2) No regulatory response (other than providing supplemental AA Report information if requested by DTSC) will be required for a selected alternative, if DTSC determines that no regulatory response is necessary to protect, prevent or limit adverse public health or environmental impacts [Section 69506.3]

### **C. Regulatory Response Process** [Sections 69506.1 (b)-(d) and 69506.12]

(1) For regulatory responses triggered by a DTSC determination or other action (including use restrictions, sales prohibitions, engineering or administrative controls, and research and development projects), DTSC will notify affected responsible entities of its proposed regulatory response determination.

(2) The proposed regulatory response determination will also be made available for public review and comment for a minimum 45-day period.

(3) After consideration of public comments, DTSC will send a final determination notice to the responsible entity(ies) and post the final notice on its website.

(4) The responsible entity must notify DTSC, and California retailers of affected consumer products, of the applicability of regulatory responses to the responsible entity's product within 30 days.

(5) The responsible entity must notify DTSC upon completion of the implementation of the required regulatory response, and (if applicable) upon completion of the implementation of the selected alternative.

(6) DTSC will post on its website a Regulatory Response Summary that identifies the regulatory response(s) for each selected alternative for a Priority Product (and each Priority Product, as applicable), and the implementation dates for the alternative product, if any, and the regulatory response(s).

### **D. Supplemental AA Report Information** [Section 69506.2]

(1) If required by DTSC, a responsible entity must provide any information DTSC determines is necessary to select and ensure implementation of regulatory responses.

(2) If required by DTSC, a responsible entity must obtain/develop and provide to DTSC information to fill one or more information gaps identified during the AA, if DTSC determines this information is needed to re-evaluate the initial regulatory response(s) imposed for the product.

### **E. Self-Implementing Regulatory Responses**

The regulations set forth specific circumstances under which the following regulatory responses will always be required, along with implementation due dates:

(1) Product Information for Consumers. Product information must be provided to consumers (within 12 months) if the alternative product contains a COC in exceedance of the applicable alternatives analysis threshold, or if the manufacturer chooses to retain the Priority Product (indefinitely or for more than 12 months pending development and distribution of the alternative product). The regulations specify the types of information that must be provided to consumers, and the mechanisms that must be used to provide the information. [Section 69506.4]

(2) End-of-Life Product Management Program. A responsible entity must establish, maintain, and fund (within 1 year) an end-of-life product stewardship program, and provide product information to consumers, if the alternative product (or the Priority Product, if the manufacturer chooses to retain the Priority Product) is

required to be managed as a hazardous waste in California at end-of-life. The requirements for the product stewardship plan and program are specified in the regulations. [Section 69506.8]

## **F. Regulatory Responses Triggered by a DTSC Determination or Other Action**

(1) Use Restrictions. DTSC may impose specified restrictions on the use of COCs in a product, or restrictions on the use of the product itself, to reduce the amount of a COC in the product, or reduce the ability of the product to contribute to or cause an exposure to the COC in the product. [Section 69506.5]

(2) Product Sales Prohibition. If the selected alternative contains a COC above the applicable alternatives analysis threshold (or if an alternative is not selected), and DTSC determines there is a safer alternative that does not contain a COC and that is functionally acceptable and technologically and economically feasible, the responsible entity must do one of the following within 1 year (or sooner if required by DTSC) [Section 69506.6]:

- Ensure that the Priority Product is no longer sold in California; or
- Submit to DTSC an AA Report that selects an alternative that does not contain a COC.

DTSC may also impose a product sales prohibition in the absence of a determination that there is a safer, functionally acceptable, and technologically and economically feasible alternative, unless the responsible entity demonstrates to DTSC's satisfaction that: (i) the overall beneficial public health and environmental impacts of the product significantly outweigh the overall adverse public health and environmental impacts of the product; and (ii) administrative and/or engineering restrictions on the nature and use of the product will adequately protect public health and the environment.

(3) Engineering or Administrative Controls. Under specified conditions, DTSC may impose requirements that control access to or limit exposure to COCs in a product to reduce the likelihood of adverse public health and/or environmental impacts. This may include controls that integrally contain a COC within the structure of a product. [Section 69506.7]

(4) Advancement of Green Chemistry and Green Engineering. DTSC may require a manufacturer to initiate a research and development project or fund a challenge grant that uses green chemistry and/or green engineering principles to: (i) design a safer alternative; (ii) improve the performance of a safer alternative; (iii) decrease the cost of a safer alternative; and/or (iv) increase the market penetration of a safer alternative. [Section 69506.9]

(5) Other Regulatory Responses. DTSC may impose one or more regulatory responses described above to situations that may differ from the specific situations described above. DTSC may periodically re-evaluate any regulatory response imposed under this provision. DTSC may also require a new AA to be performed, and new Preliminary and Final AA Reports to be submitted. [Section 69506.10]

## **G. Regulatory Response Exemptions [Section 69506.11]**

The regulations provide a process for a responsible entity to request an exemption from an otherwise applicable regulatory response (other than the requirement to provide to DTSC information supplemental to an AA Report) based on either or both of the following:

(1) The required regulatory response would conflict with a requirement of another California or federal regulatory program or an international trade agreement, in such a way that the responsible entity could not reasonably be expected to comply with both requirements. In this situation, DTSC may require implementation of a modified regulatory response that resolves the conflict.

(2) The required regulatory response substantially duplicates a requirement of another California or federal regulatory program or an international trade agreement without conferring additional public health or environmental protection benefits.

## **Existing Laws and Regulations**

### State Law

Existing law establishes the Department of Toxic Substances Control, in the California Environmental Protection Agency, with powers and duties regarding, among other things, hazardous waste disposal, underground storage of hazardous substances and waste, and the handling and release of hazardous materials.

Health and Safety Code section 25252 requires DTSC to adopt regulations to establish a process by which chemicals or chemical ingredients in consumer products may be identified and prioritized for consideration as being chemicals of concern. This process is required to include, at a minimum, consideration of: (i) the volume of a chemical in commerce in California, (ii) the potential for exposure to a chemical in a consumer product, and (iii) potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 directs DTSC, in adopting these regulations, to develop criteria by which chemicals and their alternatives may be evaluated. These criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) is required to specify. The requirement imposed on OEHHA is set out in Health and Safety Code section 25256.1. The endpoints developed by OEHHA will also be included in the Toxics Information Clearinghouse that DTSC is required to establish pursuant to Health and Safety Code section 25256.

Health and Safety Code section 25252 also directs DTSC, in adopting these regulations, to reference and use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies. However, the statute provides that DTSC is not limited to referencing and using only this information.

Health and Safety Code section 25253 requires DTSC to adopt regulations that establish a process for evaluating chemicals of concern in consumer products, and their potential alternatives, to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern. This section requires that these regulations establish a process that includes: (i) an evaluation of the availability of potential alternatives and potential hazards posed by those alternatives; (ii) an evaluation of critical exposure pathways; and (iii) life cycle assessment tools that, at a minimum, take into consideration: product function or performance; useful life; materials and resource consumption; water conservation; water quality impacts; air emissions; production, in-use, and transportation energy inputs; energy efficiency; greenhouse gas emissions; waste and end-of-life disposal; public health impacts, including potential impacts to sensitive subpopulations, including infants and children; environmental impacts; and economic impacts.

Health and Safety Code section 25253 also requires that the regulations specify the range of regulatory responses that DTSC may take following the completion of an alternatives analysis, including, but not limited to, requiring: no regulatory response; additional information to be provided to DTSC needed to assess a chemical of concern and its potential alternatives; labeling or other types of product information; a restriction on, or prohibition of, the use of a chemical of concern in a consumer product; controlling access to or limiting exposure to the chemical of concern in a consumer product; managing the product at the end of its useful life; funding green chemistry challenge grants; and any other outcome DTSC determines accomplishes the requirements of the authorizing statute.

Health and Safety Code section 25251 defines "consumer product", for purposes of the regulations required by Health and Safety Code sections 25252 and 25253, to mean a product or part of a product that is used, bought,

or leased for use by a person for any purpose. However, "consumer product" does not include: dangerous prescription drugs and devices; dental restorative materials; medical devices; packaging associated with dangerous prescription drugs and devices, dental restorative materials and medical devices; food; or pesticides. (Mercury-containing lights were exempted through December 31, 2011.)

Health and Safety Code section 25257 establishes a procedure for the protection of information submitted to DTSC, for purposes of Health and Safety Code sections 25252 and 25253, that is claimed to be a trade secret.

Health and Safety Code section 25257.1 states that DTSC is not authorized to supersede the regulatory authority of any other department or agency, and that DTSC shall not adopt duplicative or conflicting regulations for product categories already regulated, or subject to pending regulation, consistent with the purposes of Health and Safety Code sections 25252 and 25253.

Article 8 of chapter 6.5 of division 20 of the Health and Safety Code sets forth DTSC's authority and mechanisms for enforcing the provisions of chapter 6.5 (which includes the above-listed statutes) and the regulations adopted pursuant thereto.

Health and Safety Code section 58012 (added by Gov. Reorg. Plan No. 1, §146, eff. July 17, 1991) grants DTSC authority to adopt and enforce regulations for execution of its duties.

### Federal Law

The federal Toxic Substances Control Act of 1976 (TSCA) (Title 15, United States Code, commencing with Section 2601) authorizes the United States Environmental Protection Agency (USEPA) to require reporting, record-keeping and testing requirements, and to set restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides. TSCA addresses the production, importation, use, and disposal of specific chemicals. Among its provisions, TSCA requires USEPA to maintain the TSCA inventory, which currently contains more than 83,000 chemicals. As new chemicals are commercially manufactured or imported, they are placed on the TSCA inventory.

TSCA requires the submission of health and safety studies that are known or available to those who manufacture, process, or distribute in commerce specified chemicals, and allows USEPA to gather information from manufacturers and processors about production/import volumes, chemical uses and methods of disposal, and the extent to which people and the environment are exposed. However, there were 62,000 chemicals in use in 1976 when TSCA was adopted into federal law. TSCA provides a "grandfather" clause for those 62,000 chemicals. Therefore, these 62,000 chemicals are not subject to the information-gathering requirements in TSCA.

TSCA places the responsibility for conducting health and environmental impact testing on USEPA, not the producer of the chemical substance or mixture. To date, USEPA has conducted testing and published data on only 200 chemicals in the inventory of 83,000 chemicals.

In 2009, the United States Government Accountability Office, an investigative arm of the United States Congress, found USEPA's implementation of TSCA to be "high-risk" because "EPA has failed to develop sufficient chemical assessment information on the toxicity of many chemicals that may be found in the environment as well as tens of thousands of chemicals used commercially in the United States".

### **Relation to Existing Federal Law**

The proposed regulations by DTSC do not duplicate or conflict with existing federal law. The initiative for safer consumer products was developed, to a great extent, to address structural weaknesses in the federal Toxic Substances Control Act of 1976 ("TSCA", Title 15, United States Code, section 2601 et seq.). TSCA places the cost of obtaining data about chemical safety on the United States Environmental Protection Agency (US EPA) rather than requiring the chemical companies to develop and submit such information. Consequently, information about the 80,000 chemicals in U.S. commerce is severely limited and there is little to no information on the health or environmental effects of many of these chemicals.

### **Relation to Existing Federal and State Regulations**

Some of the chemicals and products that potentially may become subject to these regulations are also regulated to some degree by other existing federal or State regulatory programs. However, consistent with Health and Safety Code section 25257.1(c), these regulations contain provisions (for example, sections 69503.2(a)(3) and 69506.11) that expressly work to ensure that there is no duplication or conflict with other federal or State regulations. More specifically, the regulations require DTSC to take into consideration the nature and extent of existing or pending State or federal regulations of the same entities for the same chemicals and/or products so as to avoid duplicative or conflicting regulation under this program.

In addition, DTSC has worked closely with several sister agencies whose regulatory purview is closest to that of DTSC under these regulations. In particular, DTSC worked with OEHHA, the California Department of Public Health (CDPH), the California State Water Resources Control Board (SWRCB), and the California Air Resources Board (ARB), among other agencies, to ensure that the proposed regulations do not interfere with or conflict with any regulatory program administered by any of these agencies. Finally, DTSC has conducted extensive public outreach, including public workshops, public hearings, and public comment periods. DTSC has not received any comments during any of these opportunities for comment indicating that its regulations conflict with other State or federal regulations.

### **CONSIDERATION OF ALTERNATIVES**

DTSC must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which these regulations are proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this notice.

DTSC considered and rejected the following alternatives.

1. Do Nothing. DTSC rejected this option because Health and Safety Code sections 25252 and 25253 *require* DTSC to adopt regulations that address chemicals of concern in consumer products. So, this is not a lawful option.
2. Products and Chemical Hazard Categories Prioritization Process to Develop Safer Consumer Products. Again, after much consideration and input, DTSC determined that this approach may not fully comport with the authorizing statute. DTSC also became concerned that there was a lack of DTSC oversight during various stages of the proposed process. Many stakeholders were also very skeptical of this approach. For all these reasons, this alternative was rejected.
3. Other Options Considered in Earlier Proposed Drafts of the Regulations. DTSC released two other drafts of these regulations in 2010. During the public comment periods for the two prior formal regulatory proposals, DTSC received thousands of specific comments from hundreds of commenters suggesting other approaches to various provisions in the regulations. DTSC has again considered those comments, as well as input during

meetings of the Green Ribbon Science Panel and in other informal meetings. All of this input has led DTSC to revise various provisions that were in prior versions of both formally and informally proposed iterations of the regulations.

## MANDATES ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DTSC has made a determination that adoption of this regulation will not impose a local mandate or result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code or other nondiscretionary costs or savings to local agencies.

## COST OR SAVINGS TO STATE OR LOCAL AGENCIES, OR SCHOOL DISTRICTS SUBJECT TO REIMBURSEMENT

DTSC has made a determination that adoption of these regulations will not: (i) impose a local mandate, (ii) result in costs subject to reimbursement pursuant to part 7 of division 4, commencing with section 17500, of the Government Code, (iii) impose any other non-discretionary costs or savings on local agencies, or (iv) result in any decrease in federal funds to California as a result of these regulations.

These regulations address chemicals in products and any fiscal impact from the regulation on local agencies would likely be in the operating expense and possibly equipment line items. However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of competitive safer products readily available at competitive prices. (Please see a more detailed explanation immediately below in the Fiscal Impact section.)

Any costs incurred by local government agencies would not likely be state-reimbursable because any increase in costs would not be unique to local government and would apply generally to all entities purchasing the same products.

## COST OR SAVINGS TO ANY STATE AGENCY

### **Cost of Goods**

These regulations address chemicals in products and any fiscal impact from the regulation on State agencies would likely be in the operating expense and possibly equipment line items.

However, generally, DTSC does not expect the regulations to result in cost increases, given the wide variety of comparable safer products readily available at competitive prices. This will provide the incentive for companies that redesign their products to keep prices for the redesigned products competitive. It will also ensure that agencies, and other consumers, have a wide variety of products to choose from at competitive prices (even if the particular brand they are using is replaced with a higher price product).

It is important to note that nothing in the regulations would force an agency to buy a particular product or to replace in-use items (e.g., carpet, furniture, paint). However, these regulations will have the benefit of making more information available for state and local agencies to assist them in making their own discretionary purchasing decisions for their environmentally preferable purchasing programs.

Even if DTSC ends up banning a product, cost impacts are not expected because of the wide variety of comparable safer products readily available at competitive prices.

## **DTSC State Operations Expenditures**

The implementation activities during the first three years will include: preparing Chemicals of Concern and Priority Product lists; developing guidance for businesses and other interested parties; determining data needs; and performing legal review of: trade secret claims, chemical and product lists, various notifications and guidance and information requests.

In future years, as the program is fully implemented through all phases (chemical and product prioritization, alternatives analyses, and regulatory responses), operational and programmatic needs will increase, and DTSC will need additional resources. In these out years, businesses will begin submitting alternatives analyses and the scope of chemicals listed as Chemicals of Concern and products listed as Priority Products will expand. Thus, DTSC's resource needs will grow over time based on the need to research and evaluate additional chemicals and products, review alternatives analysis work plan and reports (including review of trade secret protection claims), develop and monitor regulatory responses, and enforce compliance with the alternatives analysis and regulatory response requirements.

## DETERMINATION OF ADVERSE STATEWIDE ECONOMIC IMPACT

DTSC has made a determination that this regulation may have a significant statewide economic impact directly affecting businesses, but that it is not expected to affect the ability of California businesses to compete with businesses in other states. It is important to note that the regulations apply with equal force to businesses in California and those outside of California. This is because the regulations apply to those businesses placing consumer products into the stream of commerce in California - regardless of the place of manufacture of those products. DTSC is unable to quantify the economic impact on businesses but has outlined factors that will increase or decrease the economic impact to businesses. Until DTSC prepares the Priority Products list, there is no way to know which or how many products will be on the list or how many businesses will be required to perform an alternatives analysis. Likewise, it is not possible to estimate how many businesses will be subject to regulatory responses.

### **Types of Businesses Affected**

Businesses impacted will primarily be those that directly or indirectly make a Priority Product available in California's stream of commerce. Businesses involved in the supply chain of Chemicals of Concern contained in Priority Products will also be impacted. To a lesser degree, businesses in the supply chain for a broader range of products (and chemicals contained those products) placed into California's stream of commerce will be impacted, but only with respect to voluntarily providing chemical and product information to DTSC upon request. The regulation impacts both out-of-state and in-state businesses. This includes: chemical and product producers, brand name manufacturers, importers and retailers in the supply chain for a Priority Product.

### **Projected Compliance Requirements**

Compliance requirements will vary from business to business depending on the products they produce, sell or import, and the arrangements that are made between the various responsible entities in the supply chain for each product. Some businesses will have no compliance requirements. Others will be required to comply with one or more of the following types of requirements: performance of alternatives analyses and submission of alternatives analyses work plans and reports for Priority Products (or submission of various notifications to DTSC in lieu of complying with alternatives analysis requirements); and compliance with regulatory responses imposed on selected products by DTSC after completion of an alternatives analysis. California retailers, in particular, for a product subject to these compliance requirements can "opt out" by ceasing to sell a Priority Product. Manufacturers and importers also have various options for less rigorous compliance than the general compliance rules depending on what actions they take regarding a Chemical of Concern present in a Priority Product.

In developing these regulations, DTSC has sought to minimize the impact on businesses by:

- Making responses to DTSC requests for information on chemicals and products optional instead of mandatory.
- Providing options to extend compliance deadlines.
- Allowing businesses to meet the requirements of the regulations through consortiums, partnerships and similar arrangements.
- Providing guidance documents and sample alternatives analyses.
- Providing exemptions for products containing only threshold amounts of chemicals of concern.
- Providing flexibility in the alternatives analysis process.
- Allowing businesses to submit alternatives analyses that do not have all the required data. Businesses would only be required to fill data gaps if DTSC requires the additional data as a component of a regulatory response.
- Allowing businesses to avoid the alternatives analysis requirement by notifying DTSC that the chemical of concern has been removed from the product.

These regulations do not require all businesses to prepare reports. The regulations also do not impose any annual or other on-going reporting requirements on any businesses.

The regulations do allow DTSC to request businesses to provide information to DTSC (using existing information or by developing new information). There is no mandate for businesses to provide such information requested by DTSC (except as part of the Alternatives Analysis process or as a regulatory response requirement). Also, responsible entities that have a Priority Product would have to conduct an Alternatives Analysis and submit work plans and preliminary and final Alternative Analysis Reports. For the reasons described under A.2 and B.1 /B.2 of this attachment, DTSC cannot estimate the costs to businesses of providing requested information or completing the Alternatives Analysis Reports until implementation is under way.

DTSC finds that it is necessary for the health, safety, or welfare of the people of California that the reporting requirements that are compulsory apply to businesses subject to these regulations.

#### COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

These regulations do not impose new responsibilities for private persons. These regulations do impact products made available for sale in California and may have the effect of increasing the costs of products identified as Priority Products or their alternatives. The impacts on consumers will be proportionate to the amount of their budget spent on Priority Products. If the Priority Products represent a small proportion of consumer expenditures, then the impacts to individual consumers should not be significant. It is anticipated that competition will protect consumers from facing higher prices for consumer products. Additionally, it is anticipated that at least some consumers will realize cost savings from the use of safer products that do not present the health threats associated with Priority Products.

As discussed above, DTSC has made a determination that this regulation will have an economic impact on businesses. However, DTSC is unable to quantify the economic impact on businesses. In particular, DTSC is unable to quantify the cost impacts on a "representative" business, as the compliance requirements will vary from business to business depending on: (i) which products are listed as Priority Products, (ii) which products

each business produces, sells, distributes or imports, and (iii) the arrangements that are made between the various responsible entities in the supply chain for each Priority Product.

## RESULTS OF REGULATORY ECONOMIC IMPACT ANALYSIS

DTSC has made the determination that the regulation may have a possible short-term minimal impact on the reduction of jobs, with a much larger potential for creation of new jobs as new materials and processes are developed. DTSC cannot estimate the number of jobs created or eliminated by the regulations.

DTSC has made the determination that the regulation may result in the creation of new businesses as new materials and processes are created, with the potential for expanded export markets for California-made products. Furthermore, current firms have time to adapt prioritized consumer products to meet regulatory requirements. Since DTSC does not know which products will become subject to the requirement to perform an alternatives analysis, it cannot predict the number of businesses that may be created or eliminated.

DTSC has made the determination that the regulation provides opportunities for growth as California businesses have access to a wider range of safer consumer products and can provide services and products for an expanding number of consumers demanding safer and greener products. It is thought that California businesses working to study, develop and promote safer and greener consumer products will benefit from these regulations.

The rulemaking may have a significant statewide economic impact directly affecting some businesses. However, the benefits of this rulemaking outweigh any adverse economic impacts. Not only does the rulemaking aim to protect public health and the environment from harmful toxic substances, it also presents the potential for the creation of new businesses and jobs and for the market expansion of safer and greener products.

## EFFECT ON HOUSING COSTS

DTSC has made a determination that there will be no impact on housing costs.

## EFFECT ON SMALL BUSINESSES (1 CCR 4)

DTSC has determined that these regulations will have an effect on small businesses. However, DTSC is unable to quantify the economic impact on small businesses for the reasons discussed above. DTSC has considered alternatives for small businesses to ameliorate the impacts of compliance with the regulations for such businesses (e.g., allowing small businesses longer time frames than other businesses to meet the requirements of the regulations). However, based upon prior public comments received on the proposed regulations, and a re-evaluation of alternatives considered, DTSC has determined that the statutes authorizing and mandating these regulations do not provide the authority to apply these regulations in a differential manner based upon the size of a business. Nonetheless, DTSC has determined that the Alternatives Analysis Guidance, that is required to be prepared by DTSC, will disproportionately work to the benefit of small businesses. This is because larger businesses may already possess, or have ready access to, expertise to assist them in complying with the regulations.

## CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) COMPLIANCE

DTSC has found this rulemaking to be exempt under the California Environmental Quality Act (Public Resources Code section 21000, et seq.). This rulemaking meets the statutory exemption available under subdivision (b)(8) of Public Resources Code section 21080. A draft Notice of Exemption is available for review with the rulemaking file and will be filed with the State Clearinghouse when the regulations are adopted.

## PEER REVIEW

DTSC is having the scientific basis of these regulations peer reviewed pursuant to Health and Safety Code section 57004.

## CALIFORNIA ENVIRONMENTAL POLICY COUNCIL REVIEW

As required by Health and Safety Code section 25252.5, DTSC will be submitting the proposed regulations to the California Environmental Policy Council (CEPC) for review after the close of the public comment period and a determination as to whether the proposed regulations require revisions.

## CONTACT PERSONS

Inquiries regarding technical aspects of the proposed regulations or CEQA documents may be directed to Odette Madriago of DTSC at (916) 323-4927 or, if unavailable, Corey Yep of DTSC at 916-445-3601. However, such oral inquiries are not part of the rulemaking record.

A public comment period has been established commencing on July 27, 2012, and closing on **September 11, 2012** for statements, arguments, or contentions regarding the rulemaking and/or supporting documents that must be submitted in writing or may be presented orally or in writing at the public hearing in order for them to be considered by DTSC before it adopts, amends, or repeals these regulations.

## AVAILABILITY OF TEXT OF REGULATIONS AND STATEMENT OF REASONS

Copies of the Notice, Initial Statement of Reasons, the text of the proposed regulations, all the information upon which its proposal is based, and the express terms of the proposed regulations are posted to DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> or may be obtained from **Kryisia Von Burg** of DTSC's Regulations Section as specified below.

After the close of the comment period, DTSC may adopt the proposed regulations. If substantial changes are made, the modified full text will be made available for comment for at least 15 days prior to adoption. Only persons who request the specific proposed regulations, attend the hearing, or provide written comments on this specific regulation will be sent a copy of the modified text if substantive changes are made.

Once the regulations have been adopted, DTSC prepares a Final Statement of Reasons which updates the Initial Statement of Reasons, summarizes how DTSC addressed comments and includes other materials, as required by Government Code section 11346.9. Copies of the Final Statement of Reasons may be obtained from **Kryisia Von Burg** at the address listed below. A copy of the Final Statement of Reasons will also be posted on DTSC's Internet site at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm>, along with the date the rulemaking is filed with the Secretary of State and the effective date of the regulations.

To be included in this regulation package's mailing list and to receive updates of this rulemaking, please visit <http://www.dtsc.ca.gov/ContactDTSC/ELists.cfm> and subscribe to the applicable electronic mailing list or e-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

Please direct all written comments, procedural inquiries, and requests for documents by mail, e-mail, or fax to:

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control

P.O. Box 806  
Sacramento, CA 95812-0806

E-mail Address: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Fax Number: (916) 324-1808

Ms. Von Burg's phone number is (916) 324-2810. If Ms. Von Burg is unavailable, please call Mr. Cordova at (916) 324-7193.

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\*The regulations provide a process for any individual or organization (including federal and other California State agencies) to petition DTSC to add/remove a chemical to/from the Chemicals of Concern list or a product/chemical combination to/from the Priority Products list. Petitions may also be submitted to DTSC requesting that an entire existing list of chemicals be added to the list of Chemicals of Concern. *[Article 4]*

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This e-mail may contain confidential material. If you are not an intended recipient, please notify the sender and delete all copies. It may also contain personal views which are not the views of CQ Roll Call or its owner, The Economist Group. We may monitor e-mail to and from our network. For company information go to <http://legal.economistgroup.com>.

October 11, 2012

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

COMMENT ON SAFER CONSUMER PRODUCTS REGULATIONS  
DSTC REFERENCE NO.R-2011-02, OAL FILE NUMBER Z-2012-0717-04

MWS Wire Industries is a wire manufacturing and distribution business operating in California since 1968. The company employs 45 people as a supplier of high quality, high reliability products to manufacturers in the medical device, aerospace, automotive and other critical industries.

The company uses solvents with hazardous properties that sooner or later may be Chemicals of Concern subject to the proposed Safer Consumer Products regulations. In this regard MWS Wire emphasizes that use of hazardous materials in the workplace is already subject to substantial state and federal worker protection regulations: providing detailed hazard information, initial and periodic training of workers in safe handling procedures, definitive OSHA PEL's, protective equipment, engineered safety measures and controls and so on. In view of these worker protections, MWS Wire strongly objects to the portion of section 69503.2 Priority Products Prioritization Factors that lumps in workers with "customers, clients, and members of the general public who use, or otherwise come in contact with, the product or releases from the product in the home, workplace, or other locations;" None of these groups have the benefit of training and other safeguards already noted that prepare and protect workers using hazardous materials. To include workers in this way is misguided and violates the express requirement that these regulations not duplicate existing ones.

For the same reasons the company objects to Section 69501.1 Definitions, (58) "Sensitive subpopulations," which includes "workers with greater exposures due to the nature of their occupation." Leaving aside the fact that including workers who are exposed to hazardous chemicals duplicates existing worker protection regulations, what does "greater exposure" mean? Certainly a worker who has been given information, training, protective equipment and a properly engineered work environment has far less exposure and is at far less risk than infants, children, pregnant women and the elderly who lack basic protections. It is absurd to classify workers with significant knowledge, training and other protections with people that have none of these advantages.

Since the first electrical wire coatings were formulated a century ago, the industry has invested in research for alternatives to expensive solvents but thermal and electrical performance has proved inferior when less toxic chemicals and production methods have been tried. The solvents in use today are essential for producing high reliability products that meet stringent safety and performance standards mandated by our customers and third parties such as Underwriters Laboratories.

MWS Wire Industries urges DTSC to tightly focus the Safer Consumer Products regulations where it will have the greatest positive impact: on household, personal hygiene and children's products, cosmetics and the like. The current attempt to broadly encircle all chemical users, including manufacturers of products critical to industry, could have the unintended consequence of strangling businesses while doing little to make consumers safer.

Sincerely,

A handwritten signature in blue ink, appearing to read "Kenneth R. Goss". The signature is fluid and cursive, written over a white background.

Kenneth R. Goss, Operations Manager  
MWS Wire Industries

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Via e-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

On behalf of the National Association of Chemical Distributors (NACD), I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

NACD is international association of 400 chemical distributors and their supply-chain partners. NACD represents more than 85% of the chemical distribution capacity in the nation and 90% of the industry's gross revenue. Members of NACD operate in every region of the country through approximately 1500 facilities. As leaders in their communities, NACD members are predominantly small regional businesses. The typical member has 26 employees and \$26 million in annual sales.

NACD members meet the highest standards in safety and performance through mandatory participation in Responsible Distribution, NACD's third-party verified environmental, health, safety, and security (EHS&S) program. Through Responsible Distribution, NACD members demonstrate their commitment to continuous performance improvement in every phase of chemical storage, handling, transportation, and disposal operations. Through Responsible Distribution, NACD members have achieved a strong safety record. Member companies' safety rating is 80 percent better than non-member companies in the Chemical & Allied Merchant Wholesale Industry and more than twice as good as all manufacturing combined.

As a member of the Green Chemistry Alliance (GCA), NACD appreciates the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective chemicals management system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program in order to determine what works and does not work and to make adjustments accordingly. However, beyond this, NACD believes that the DTSC is proposing a regulatory scheme far in excess of what is necessary to conduct the initial phase. NACD, in concurrence with GCA, strongly recommend DTSC consider a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

NACD is gravely concerned that the Safer Consumer Product Alternatives Regulation as proposed falls well short of meeting the practical, meaningful and legally defensible objectives that DTSC Director Raphael set out when she was appointed to implement this monumental initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879 and SB 509, 2008). The intent of the underlying statute is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

Regulatory uncertainty is one of NACD's most serious concerns about the proposed regulation. As currently drafted, the proposal gives the DTSC unprecedented latitude to implement the program, providing the Department with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply. The current proposal would establish an all-encompassing program that far exceeds the more modest intent of a practical approach. Indeed, in addition to everyday consumer products, virtually all commercially available products and their packaging will be subject to the regulation.

Because this entire regulatory program builds off of each of the prior regulatory actions, it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the preceding actions are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. This piecemeal approach to addressing concerns only exacerbates the tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute, NACD, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on ***exposure*** and ***hazard***, and it ***must avoid duplication and conflicting regulatory requirements***.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports a two-step approach that begins with "chemicals under consideration" and then proceeds to "chemicals of concern." In this regard, NACD concurs with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next craft a manageable process focusing on chemicals that exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by the U.S. Environmental Protection Agency (EPA) and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

It is difficult to reconcile the costs and complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would result in exorbitant costs to all entities doing business in California and would necessitate a huge new government program with a substantial budget requirement. This would only exacerbate California's economic and budgetary challenges.

To date, DTSC has failed to clearly identify potential compliance costs for businesses and individuals, the number of businesses impacted, the number of small businesses that will be impacted, nor the number of businesses and jobs that will be created or eliminated as a result of the regulation. This is unconscionable for such a far-reaching regulation, particularly in a weak economy.

For these reasons, NACD urges the DTSC to delay implementation of the Safer Consumer Products Regulations until a clearer and more reasonable regulatory approach is developed and a more thorough assessment of the economic impacts is completed.

Thank you for the opportunity to comment on this issue. NACD appreciates your consideration of our concerns. If you have any questions or need additional information, please feel free to contact me.

Sincerely,



Jennifer C. Gibson  
Vice President, Regulatory Affairs  
NATIONAL ASSOCIATION OF CHEMICAL DISTRIBUTORS  
1555 Wilson Boulevard, Suite 700  
Arlington, VA 22209  
(703)527-6223

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



National Electrical Manufacturers Association

Representing Electrical and Medical  
Imaging Equipment Manufacturers  
[www.nema.org](http://www.nema.org)

## SUBMITTED BY EMAIL

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**RE: NEMA Comments on Proposed Regulation for Safer Consumer Products - Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04)**

Dear Ms. Von Burg:

The National Electrical Manufacturers Association (NEMA) is the principal trade association representing the interests of the US electrical products industry.<sup>1</sup> NEMA members have more than 120 facilities (headquarters, manufacturing, research, sales or distribution offices) in California and are a significant contributor to California's manufacturing and technology sector.

NEMA appreciates the opportunity to respond to the proposed Safer Consumer Product Alternatives Regulation issued by the Department of Toxic Substances Control ("Department" or "DTSC") in July 2012. We appreciate the considerable effort DTSC continues to invest in developing an efficient and effective regulatory system for hazardous chemicals, as authorized by the underlying California statutes. The Department's announced intention to limit the scope of the program initially to five Priority Products is a step in the right direction.

Overall, however, NEMA continues to view this unprecedented state regulation with alarm as it lacks focus and places virtually no boundaries on the State's discretion to regulate innumerable substances in an untold number of products. We are most concerned with the absence of scientific rigor at key decision points and insufficient emphasis on controlling actual risks to human health and the environment, rather than simply reacting to the presence of potentially hazardous chemicals. In addition, the sheer breadth of the rule and its provisions remains overwhelming – the program **starts with** an initial roster of 1200 Chemicals of Concern and the regulation provides that DTSC may add chemicals that meet only one of 16 factors. The department may then consider 28 factors set out in the rule to determine "Priority Products." In tandem, these provisions grant DTSC extraordinary latitude in selecting product/chemical combinations as a priority product.

Some of NEMA's other concerns with the proposed rule include the following.

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<sup>1</sup> See [www.nema.org](http://www.nema.org)

- Given the scope, complexity, and likely compliance costs imposed by the system described in the proposal, NEMA questions whether it will generate benefits in terms of improved health and environmental safety that are anywhere near commensurate. Costs will be incurred not just by manufacturers but also by California taxpayers forced to fund a huge new government program with a substantial budget requirement.
- The lists cited in Article 2 as the basis for selecting Chemicals of Concern are not presented in proper context. For example, Category 1; Endocrine Disruptors is only a working list that offers no conclusions on adverse impact. Therefore the listed chemicals may or may not be true endocrine disruptors. The scientific rigor underlying these varied sources no doubt ranges considerably, and some organizations define concepts such as “carcinogenicity” differently. It is thus inappropriate to combine many disparate lists without distinction or qualification as the basis for target substances in this rule.
- Section 69506 of the proposed rule provides that DTSC will adopt regulatory responses that “*maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible.*” It also requires that when selecting regulatory responses, the Department shall give preference to responses “*providing the greatest level of inherent protection,*” where ‘inherent protection’ is defined to mean “*avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls.*” NEMA believes these provisions may conflict with the statutory provision in HSC Section 25253, where the legislature established the standard for evaluating COCs in consumer products and their potential alternatives “*to determine how best to limit exposure or to reduce the level of hazard*” posed by a COC. This is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection.
- Parties responsible for Priority Products will be required to conduct Alternatives Assessments (AA) and submit preliminary and final reports to DTSC within a narrow timeframe. This will undoubtedly be a complicated and costly effort that will impose an especially heavy burden on small and medium sized enterprises. The Department notes in the Initial Statement of Reasons document that it conducted an economic impact analysis in accordance with Government Code sec. 11346.3(b).<sup>2</sup> The analysis is limited to three short paragraphs and contains no mention of expected industry compliance costs and their impact on regulated parties – presumably because this metric is not specifically required by this section of the California Code. This is regrettable since the mission and scope of the regulation clearly will force numerous companies to take action and incur expenses. NEMA strongly urges DTSC to provide a more substantive assessment of the costs and benefits of this proposed rule.
- The rule now contains a “Threshold Exemption” that can serve to waive the AA requirement on for some manufacturers, but it is unclear how the threshold level will be determined. Will there be a scientific process? DTSC will evidently set thresholds case-by-case, but it is not a risk-based process.

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<sup>2</sup> Department Reference Number: R-2011-02 - Office of Administrative Law Notice File Number: Z-2012-0717-04, pg. 4

- Alternatives Assessments also include an “Economic Impacts” component. Responsible parties must “*evaluate and compare the economic impacts of the Priority Product and the alternatives.*” If the outcome of the comparison supports retaining the priority product, the responsible party must “*take into account **all projected direct and indirect cost impacts** during the life cycle of the product and the alternatives being considered*” (emphasis added). This is so broad as to be unworkable. It is unclear how any manufacturer could even estimate all the factors involved. Furthermore, there is insufficient agreement on the methodologies for producing useful, reproducible results – which in any event will only be estimates.
- § 69506.8 of the rule describes End-of-Life Management Requirements as one of the regulatory responses available to the state under the rule. This regulatory option would involve a “Comprehensive Product Stewardship Plan” that includes, among other elements, “*Anticipated resources needed to implement and sustain the plan, including identification of any third-party product stewardship organization **collecting and administering a fee to fund the stewardship program***” [Subsec. (a)(2)(A)6, emphasis added]. This provision, while well meaning, fails to comply with the state action doctrine and is therefore insufficient to authorize the use of a fee by manufacturers to fund a product stewardship program. Any effort by manufacturers to do so would risk violation of federal antitrust regulations.
- The proposal as currently drafted threatens vital intellectual property that engenders innovation, requiring that manufacturers submit more information than is necessary and providing absolute discretion to the Department to make decisions about trade secret claims.

In summary, NEMA generally concurs with the recommendation consistently set forth by the Green Chemistry Alliance that DTSC consider a more focused program, with emphasis on the substances in consumer products that pose true risks for human health and the environment based on hazard, exposure and the likelihood of harm.<sup>3</sup> We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

If you have questions about these comments or wish to discuss our positions further, please contact Mark A. Kohorst of my staff at 703-841-3249 or [mar\\_kohorst@nema.org](mailto:mar_kohorst@nema.org). Thank you again for your consideration and willingness to consider the concerns of regulated parties.

Very truly yours,



Kyle Pitsor  
Vice President, Government Relations

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<sup>3</sup> See [www.greenchemistryalliance.org](http://www.greenchemistryalliance.org)



## NATIONAL SHOOTING SPORTS FOUNDATION, INC.

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**JAKE MCGUIGAN**  
DIRECTOR,  
GOVERNMENT RELATIONS

October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives  
Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22  
of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

Dear Ms. Von Burg:

The National Shooting Sports Foundation ("NSSF") is the trade association for America's firearms, ammunition, hunting and recreational shooting sports industry. Its mission is to promote, protect and preserve hunting and the shooting sports. NSSF has a membership of more than 7,000 manufacturers, distributors, firearms retailers, shooting ranges, and sportsmen's organizations. Our manufacturer members make the firearms used by law-abiding California sportsmen, the U.S. military and law enforcement agencies throughout the state.

On behalf of NSSF, I respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

The long-standing firearms industry is a proud part of California history yet continues to be targeted with legislation and regulations that infringes on their ability to do business. Many manufacturers in the state have been courted by firearm-friendly states and offered tax incentives and economic benefits to relocate. However, these companies have rebuked these offers in order to still be a part of the California business environment.

The firearms industry has contributed over \$3.6 billion in economic activity to California in 2011, employs more than 10,800 people in the state and generates an additional 4,700 jobs in supplier industries. In these difficult economic times, the firearms industry is still one of the few industries that has grown its profits while also contributing increased tax revenues to the state (to the tune of \$251 million). The firearms business is a highly regulated entity on both the state and federal level. It is unfortunate that precious time is focused on regulations which will severely impact our businesses operating and selling lawful products throughout the state.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort DTSC has once again invested in its latest effort to develop an efficient and effective regulatory system.

NSSF is pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support.

The firearms industry is already subject to complying with federal standards with respect to its manufacturing process and the different chemical levels it is allowed to employ. Creating a different set of standards will create confusion and make it almost impossible to comply with. The duplicative nature of the regulations could cause situations where not only could companies not manufacture certain products in the state, but also many of our members will not be able to sell into the state.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety that it is likely supposed to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement not to mention that many of the standards have already been set in place by federal regulators.

NSSF believes that the flexibility that the proposed regulations offers the Department with respect to implementing the program and developing *de minimis* levels could be useful for industries that already have to comply with federal standards. The Department could use this flexibility to develop exemptions based upon already derived federal levels. The exemptions could allow for a much smoother and efficient process for many of the already highly regulated industries. America's firearm and ammunition manufacturers have a long and proud history of supporting science-based results whether dealing with wildlife management or the manufacturing of our products. This concept has been championed by our industry, and we will continue to aggressively support science based steps and we believe that the Department should do so as well when crafting regulations. The current proposal would establish an all-encompassing program that seems to exceed the original intent. Not only will our major products be impacted, but also the very packaging we use to market and sell the products.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

Ms. Krysia Von Burg

October 11, 2012

Page 3 of 3

As an industry we are extremely disappointed that the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008). The regulations seem based more on politics and threats of litigation than science. The proposed regulations will only do more harm to the California business environment than increasing public safety.

The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

NSSF, representing hunters and sportsmen organizations around the nation, takes great pride in supporting science-based research and regulations. The hunters and shooters that we represent are the largest financial supporters of conservation programs throughout the United States. The industry is committed and understands, perhaps better than anyone else, the importance of conserving resources and protecting our environment.

The financial burden that is created by these regulations and others makes it increasingly more difficult for manufacturers to continue their livelihood, create jobs and tax revenue for the state.

We appreciate your consideration of our concerns. For further information or questions, please contact our legislative advocate, Kathryn Lynch, at (916) 443-0202.

Thank you!

Sincerely,



Jake McGuigan

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



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[www.NaturalProductsAssoc.org](http://www.NaturalProductsAssoc.org)

October 11, 2012

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

RE: Safer Consumer Product proposed regulations: California Regulatory Notice Register (Z-2012-0717-04).

The Natural Products Association (NPA) is submitting this letter as general comment to the Safer Consumer Product proposed regulations: California Regulatory Notice Register (Z-2012-0717-04). NPA was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of nutritional foods and natural products. The NPA is a non-profit 501(c)(6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers and we build strong markets to fuel industry growth. We are the oldest and largest trade association in the natural products industry representing over 1,900 members accounting for over 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA is concerned about the detrimental impact that the regulations as written will have on association members and the natural products industry as a whole. The comments below outline our main concerns with the regulations and offer our suggestions for how they can be improved. Thank you very much for the opportunity to comment.

The petition process included in the regulations allows persons to circumvent the intended careful, linear DTSC process based on a neutral, agency evaluation of priorities. What is to stop 100 petitions requesting additional priority products from being filed immediately? This could in effect just reopen the rule-making process. Also, the regulated community will step back to the very “product by product” and “chemical by chemical” chaotic regulatory process the Green Chemistry Rules aim to preempt. Petitions to add priority products or chemicals of concern can be filed for any reason, including illegitimate reasons, such as: to attack the reputation of competitor products; to create an adverse public record; or the result of misinformation or sensationalism in the press. This process would derail the limited approach DTSC now advocates.

NPA recommends that DTSC consider suspending the petition process to add priority products or chemicals of concern for 5–7 years to allow the DTSC ordered priorities and process to unfold. NPA would also recommend that petitioners be required to document technical or scientific qualifications pertinent to the subject of the petition as well as certify (perhaps under penalty of perjury) that the petitioner has no direct personal financial stake in the outcome of the petition process. This would tend to limit petitions to governmental authorities, trade associations, collective bargaining units, established non-profits and other collective organizations where vetted, mainstream positions are more likely to be advocated.

The retailer burdens included in the regulations are unreasonably heavy and inevitably will lead to negative consequences. First, not all retailers can continuously monitor websites for priority products and other proceedings. Many retailers do not have the financial resources, personnel or the complex background skills to conduct such monitoring. Second, if DTSC forces retailers to identify themselves as sellers of priority products, we predict the vast majority of retailers simply will refuse to sell the products. Thus, DTSC’s designation of a priority product is effectively an immediate product sales ban. Few retailers will a) absorb the burden of seeking legal advice on their obligations under this new law; b) file with DTSC and monitor developments on a priority product; c) have the resources to implement DTSC’s

determinations (e.g., product recalls or quarantines); or d) conduct an alternatives assessment. Thus, even before anyone begins an alternatives assessment, the priority product may effectively disappear from many retailer shelves resulting in a de facto product ban. Consumers may well be denied safe, lawful and appropriate products simply because retailers cannot and will not take on the burdens of the law.

NPA recommends that DTSC suspend retailer duties of any sort until the alternatives assessment process is complete. Retailers should never be charged with conducting alternatives assessment. If products are later banned, or recalled, DTSC can send notices to the public in an effort to cover all such items.

The alternatives analysis process is very complex, cumbersome, costly and almost certainly beyond the financial and technical ability of many small- to medium-sized manufacturers. Again, the likely outcome is that a priority product will be withdrawn from the market, as the economic and other costs would be prohibitive. The notion that similar parties can band together to have “group alternative analyses” is likely to be unworkable. First, competitors all have intellectual property and other confidential information that they will be loathe to share with each other in support of a collective effort. Second, most competitors distinguish their products, meaning the same products will not have uniform properties, making collective assessments difficult, prone to inaccuracies as they relate to any one product, or impossible. “Free rider” problems will arise when only some parties will fund an alternatives analysis, but many more can rely on the results. Again, the likely result of these difficulties will be withdrawal of the product before there is any proof the product is anything other than safe, lawful, and of benefit to consumers.

NPA recommends a streamlined alternatives analysis option for small- to medium-sized manufacturers or other businesses, perhaps involving a form that could be completed by a non-expert based on available information to the party.

Overall, the regulations as currently written are so burdensome on both DTSC and the regulated community that it begs the question of whether industry can submit, and DTSC can evaluate, alternatives assessments in a timely manner. This inherent complexity renders the rule inoperative from day one in practical effect. Why not start with a small pilot? DTSC could evaluate one product for just one chemical of concern to give an example of how the rules actually work before implementing the full program.

NPA appreciates your consideration of our comments.

A handwritten signature in black ink that reads "Cara Welch". The signature is written in a cursive, flowing style.

Cara Welch, Ph.D.

Sr. Vice President, Scientific & Regulatory Affairs

Natural Products Association

## GCREgs@DTSC

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**From:** Jane Newman <janewashere@hotmail.com>  
**Sent:** Tuesday, October 02, 2012 8:08 AM  
**To:** GCREgs@DTSC  
**Subject:** consumer protection

We need legislation to protect us from dangerous chemicals in industrial use. If Europe can do this, so can we.  
Thanks-Jane Newman

**From:** peterbnewman <peterbnewman@marincounty.net>  
**Sent:** Sunday, October 07, 2012 5:45 PM  
**To:** GCREgs@DTSC  
**Subject:** public comment re chemicals of concern plan

Dear California Department of Toxic Substances Control --

First off, I would like to know if this is the correct medium (email) and location ([gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)) to make comment on your plan re "chemicals of concern"?

I could not find anything at your site that clearly states where and how to make comment -- only a notice that the comment period had been extended to October 11th, and the above email address at the end of that page.

If this is the correct way/place, hooray.

If not, please forward this to who/how/where it should have gone.

Here are my comments:

1) I am disappointed that your site does not provide more-useful information to the new visitor (me) -- and that there is no clear place to make comment on current issues under consideration that gives me the impression that you do not really welcome public comment

2) So to validate my comments I will first state my bona fides: I am not chemically sensitive (to my knowledge), but I did suffer a cancer (RCC) 10 years ago that is environmentally-induced -- and is on the rise, and is believed to be chemically-induced.

I also have a degree from UC Berkeley in the sciences, and part of an MBA from SFSU. I am a businessman and also a science nerd and I consider myself both well-informed and fairly reasonable.

I guess I should also say that I own stock in most of the major chemical corporations in this country (via the S&P500), plus I have owned a number of specific companies on and off over the decades -- and currently own about \$100K in various chemical company stocks.

3) Having said that, I want to be quite specific and somewhat harsh in my criticism: The chemical industry has been given a carte blanche to experiment on the unsuspecting American public for 60+ years now. They have added hundreds of thousands of new chemicals to our bodies and our environment. It is long, long past time that they be more-closely regulated -- and one fine place to start is by making them disclose to the public what is in our stuff. Some of us are label-readers and know enough to understand what they may mean. Others are entitled to a crack at protecting themselves even if they are not as well-equipped to understand this material.

Plus, it makes zero sense in the age of information to withhold data that we are entitled to know and that might well be germane to our health. Obviously I believe in capitalism -- but I also hope for the free flow of information that is supposed to make markets efficient and capable of making wise decisions. To accomplish that you must release all possible helpful information.

Additionally, I am aghast and disappointed to find the Democratic leadership of this state easing off on the chemical companies when it is clear that is exactly what the public does not want. We are aware of that there are too many chemicals in our lives -- we need data and disclosure to help us use only the ones we must.

Lastly, although I am not a parent, I am an uncle... I hate the idea that my nephews and nieces will continue to be subject to the largely unregulated chemical experiment that is this industry's standard practice -- and I hate the idea that that generation will suffer even more cancers (or other diseases) if something is not done to stop this assault.

The first step in stopping an assault is to identify the attacker and the weapons -- so please strengthen, not weaken, the plan to fully disclose "chemicals of concern".

Thank-you for your attention to my concerns.

Sincerely,

Peter B. Newman



BTW, I also do not belong to any anti-chemical-industry group -- or any other radical political groups. And I was not encouraged by anyone to write this letter. I read an article in today's SF Chronicle about this plan, and that the comment period had been extended, and I decided to add in my two cents.

Maybe the last thing I should say is that, before finishing at UC Berkeley I was a pre-med student at the Uof Pennsylvania -- where I managed to ace my year-long Chem 101 course final. I was only one of three people in a class of 600 to do that. So, I am not un-familiar with the benefits chemicals have brought to the modern world. But I am also quite clear that the industry has been far too under-regulated. It has long been clear that we absorb chemicals in ways other than solely through food or drugs -- and yet we are far more protected from bad meat or bad drugs while thousands of dangerous, unregulated, and un-checked chemicals wreak their quiet, slow havoc on us and the environment.

And that is coming from a rich white guy who was a third generation corporate kid, and who owns guns. Yeah, I also live in Marin. And I vote Democrat.

This is not about politics -- it is about human (and environmental) health. There is no excuse for hiding the truth from us: not when the results can be so significant.

PBN



*Celebrating 75 Years  
of Energy Efficiency*

**VIA E-MAIL**



October 11, 2012

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

RE: Comments of the North American Insulation Manufacturers Association (“NAIMA”) on the California Department of Toxic Substances Control’s Proposed Regulation: Safer Consumer Product Alternatives (Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04)

Dear Ms. Von Burg:

## INTRODUCTION

The North American Insulation Manufacturers Association (“NAIMA”) appreciates the opportunity to submit written comments on the California Department of Toxic Substances Control’s (“DTSC”) revised draft regulation entitled “Safer Consumer Product Alternatives.” NAIMA appreciates that DTSC has modified its approach from the first draft. Unfortunately, these modifications did not sufficiently mitigate many of the unnecessary burdens on businesses and California’s economy resulting from the proposed regulations or increase significantly benefits to public health and the environment. The proposed rule as revised could do significant harm to California’s economy.

Most importantly, the revised draft continues to give untested products and substances an undeserved and unmerited pass as acceptable substitutes for thoroughly tested and researched products and substances. DTSC should never assume that untested products or substances are safe; it can frequently be the case that the reason why no data exist on a particular product is that its manufacturers are careful not to generate any data regarding product hazards.

NAIMA is the association for North American manufacturers of fiber glass, rock wool, and slag wool insulation products. NAIMA promotes energy efficiency and environmental preservation through the use of fiber glass, rock wool, and slag wool insulation, and encourages the safe production and use of these materials. NAIMA’s members operate four insulation manufacturing plants in California and also import significant volumes of insulation into the State. Fiber glass insulation products are used widely throughout the State of California. NAIMA’s members’ insulation products are sold at home improvement stores throughout the State and installed by homeowners as weekend do-it-yourself projects. Their products are also installed by professional insulation contractors in both new and existing homes and commercial

buildings. Therefore, the DTSC's revised regulation is highly relevant to NAIMA and its manufacturing members.

#### DTSC's DRAFT RULE FAVORS UNTESTED AND UNPROVEN PRODUCTS

NAIMA is concerned that the revised regulations will be implemented in such a way that replacement materials will be approved for use over listed materials because there is no data on the potential health effects of those replacement materials. Lack of data does not necessarily equate to safe.

Have supposedly "safe substitutes" been tested? There is no scientific data available for many materials and products. Many materials and products have never been reviewed by expert panels such as the International Agency for Research on Cancer ("IARC") and the Department of Health and Human Services ("HHS") to make a decision on whether they present health hazards. For example, IARC and the National Toxicology Program ("NTP") do not even review a substance or product unless there is ample data to evaluate. NTP mandates that substances to be nominated for review possess appropriate background information and relevant data.<sup>1</sup> Similarly, IARC's selection of agents for review requires that published data on the potential carcinogenicity of the agent be available for review.<sup>2</sup>

The necessity of data to form a conclusion or listing is obvious. Yet DTSC seems to have ignored the simple fact that many producers of agents/substances purposefully decide to avoid testing or research on its products/substances. The reason is the likely avoidance of ending up on a list such as the ones relied upon by DTSC. Therefore, DTSC's regulation gives preferential treatment to untested products.

An untested product does not mean it is a safe product.<sup>3</sup> A system wherein untested products are treated as though they are safe and not regulated should not form the basis for a decision on whether a product is banned. DTSC should avoid awarding preferential treatment to a product or substance simply because a particular product's manufacturer has neglected responsible product stewardship and refused or failed to test its product. Indeed, the failure of a particular product or substance to be adequately tested by its manufacturer should be a critical factor in determining that a product is not an acceptable alternative.

Sincerely,



Angus E. Crane  
Executive Vice President, General Counsel

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<sup>1</sup> Process for Preparation of the Report on Carcinogens, Page 1 (January 3, 2012). <http://ntp.niehs.nih.gov/NTP/RoC/Thirteenth/Process/FinalRoCProcesswithFig.pdf>.

<sup>2</sup> World Health Organization International Agency for Research on Cancer, "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans" Volume 99, Some Aromatic Amines, Organic Dyes, and Related Exposures, Page 12 (2010). <http://monographs.iarc.fr/ENG/Monographs/vol99/mono99.pdf>.

<sup>3</sup> J.M.G. Davis, "The need for standardized testing procedures for all products capable of liberating respirable fibres; the example of materials based on cellulose," *British Journal of Industrial Medicine* 1993; 50: 187-190.



October 11, 2012

Via E-Mail

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of  
Division 4.5 of Title 22 of the California Code of Regulations (Z-  
2012-0717-04) (July 2012)

Dear Ms. Von Burg:

The North American Metals Council (NAMC)<sup>1</sup> submits this letter in response to the California Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Alternatives regulations of July 2012. NAMC's comments, similar to our December 29, 2011, comments on a previous draft of this regulation, focus on the proposed process to identify chemicals of concern, which, as we understand it, will then be used to identify priority products for review under the regulations. Because metals, metal compounds, and metal products exhibit unique characteristics it is inappropriate to evaluate them using the general hazard evaluation principles applied to organic chemicals.

As we understand, the regulations would apply to all chemicals that exhibit a hazard trait and that are present in consumer products in California. According to the proposed regulations, hazard traits are defined in Division 4.5, Title 22, California Code of Regulations -- Chapter 54, *Green Chemistry Hazard Traits for California Toxics Information Clearinghouse*. That document includes both environmental persistence and bioaccumulation as hazard traits. As noted in our previous comments, hazard factors for a metal depend on -- among other things -- the specific metal, the form of the metal and/or metal compound, the bioavailability of the metal to particular organisms, and the organism's ability to regulate and/or store the metal. Certain environmental endpoints used to screen, assess, or prioritize organic compounds -- particularly bioaccumulation and persistence -- are not appropriate for assessing the hazard of metals. We urge DTSC to highlight specifically in the

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<sup>1</sup> NAMC is an unincorporated, not-for-profit group of metals-producing and metals-using associations and companies formed to provide a collective voice for the North American metals industry on science and policy-based issues that affect metals in a generic way.  
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North American Metals Council

Ms. Kryisia Von Burg  
October 11, 2012  
Page 2

final regulations that metal substances will require specialized review and to reference the U.S. Environmental Protection Agency's (EPA) *Framework for Metals Risk Assessment* as the guideline that DTSC will use in its evaluation of such substances.

NAMC is also concerned with the proposed authorities DTSC has reserved for itself to run this program. With the discretion DTSC has built into the process at multiple decision points, there appears to be little to no opportunity for industry or impacted stakeholders to fully understand what must be done to comply with the regulation. Given that virtually all commercially available products and their packaging will be subject to the regulation, this lack of transparency will likely cause chaos among the regulated community. Indeed, rather than achieving the objective of innovation of safer consumer products, the regulations as proposed will create an unpredictable framework that will increase uncertainty in the business community.

NAMC supports the recommendation by Senator Michael J. Rubio (D-Shafter) to delay these regulations until a more thorough economic impact analysis is available. As previously noted, given that this regulation will impact virtually all products in California, a true sense of the impact to California businesses and communities is essential.

Thank you in advance for your review and consideration of these comments. If you have any questions or require additional information, please contact me at 443-964-4653 or [kroberts@namc.org](mailto:kroberts@namc.org).

Respectfully submitted,

Kathleen M. Roberts  
Executive Director  
NAMC

cc: The Honorable Matt Rodriguez, Secretary, CalEPA (via e-mail)  
Miriam Ingenito, Deputy Secretary, CalEPA (via e-mail)  
Kristin Stauffacher, Assistant Secretary, CalEPA (via e-mail)  
Nancy McFadden, Cabinet Secretary, Office of the Governor (via e-mail)  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor (via e-mail)  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor (via e-mail)  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor (via e-mail)

## GCREgs@DTSC

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**From:** Kevin O'Brien <kmobrien1@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 9:49 AM  
**To:** GCREgs@DTSC  
**Subject:** dangerous chemicals

**Categories:** Comment

Our family feels strongly that you should follow through on the process to identify, regulate and remove from legal use those 1200 dangerous chemicals identified and included in the state law from 2008. Thank you, Kevin O'Brien

## GCREgs@DTSC

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**From:** PALMER JR., DONALD G <dp2697@att.com>  
**Sent:** Tuesday, October 02, 2012 12:31 PM  
**To:** GCREgs@DTSC  
**Subject:** Opposed to Proposed SCP Regulations

Dear DTSC,

I write to oppose DTSC's proposed Safer Consumer Products regulations.

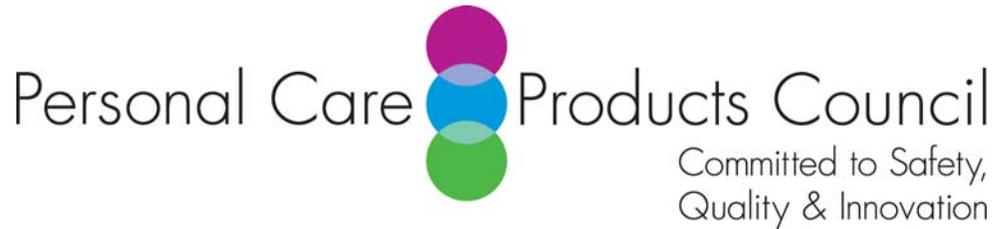
The proposed regulations go far beyond the intent of the enabling legislation, both as to the scope of the chemicals of concern to be identified and the compliance obligations required of manufactures, importers, and retailers of consumer products in California. The scope of the regulations are so broad and complex that they risk failing to achieve the objectives of the original legislation - identify dangerous chemicals in consumer products and mitigate exposure to consumers, including the potential use of safer alternatives where feasible. Instead, these regulations focus on potentially thousands of chemicals and literally every form of manufactured product used by consumers in this state, from cars and trucks to household cleaners and everything in between!

The cost of compliance by businesses affected by these regulations is likely to be staggering; indeed, even DTSC could not effectively identify the potential cost impact of these regulations.

As a California resident, consumer, and responsible citizen of this state, I support making consumer products safer for use by consumers. However, I believe the methods chosen by DTSC in this regulation will only lead to confusion, increased costs to businesses and consumers, and simply fail in its mission to get the most dangerous chemicals out of consumer products in the shortest amount of time.

Respectfully,

Donald G. Palmer, Jr., Esq.  

October 11, 2012

**By Electronic Mail**

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
[gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**RE: Safer Consumer Products Proposed Regulations**

Dear Ms. Von Burg:

The Personal Care Products Council (Council)<sup>1</sup> is pleased to submit the following comments on California's Safer Consumer Products proposed regulations that were developed by the Department of Toxic Substances Control (DTSC) and publicly released on July 27, 2012. Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in California and throughout the United States, and therefore have a strong interest in the scope and applicability of these regulations.

**INTRODUCTION**

Since the inception of California's Green Chemistry Initiative in May 2007, the Council and its members have engaged California legislators, regulators, non-governmental organizations, and the business and scientific community to provide thoughtful insight, ideas, and comments about Green Chemistry. The Council has hoped to develop a practical and effective regulatory framework that would promote sustainable innovation while making meaningful improvements to the protection of human health and the environment.

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<sup>1</sup>Based in Washington, D.C., the Council is the leading national trade association representing the \$250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products that millions of consumers rely on everyday, from sunscreens, toothpaste, and shampoo to moisturizer, lipstick, and fragrance, member companies are global leaders committed to product safety, quality, and innovation.

Although the Council objected to many provisions in the draft regulations,<sup>2</sup> released on October 31, 2011, it is evident from the recently released proposed regulations that DTSC addressed some of our concerns and made important modifications. The Council applauds, for example, the removal of the Safe Cosmetics Act as a source for the Chemicals of Concern list; and the elimination of the distinction between “assembled” and “formulated” products; and acknowledges that while the timelines for conducting an alternative analysis remain shorter than what is necessary they are a step in the right direction. Despite positive changes, however, there remains work to make the proposed regulations more effective and less burdensome for the regulated community. Therefore, in this spirit of cooperation, the Council respectfully submits the following comments, both general and specific, in the hopes that DTSC will consider them and make our suggested changes to the regulations before issuing the final regulation.

#### **KEY POINTS**

Below are the primary points that the Council raises:

- 1. OTC Drug Exemption.** OTC drugs, like prescription drugs, are comprehensively regulated by FDA and should be exempt from these regulations.
- 2. Initial List of Chemicals of Concern.** The “list of lists” chemical identification process proposed by DTSC is fundamentally flawed and scientifically indefensible.
- 3. Alternatives Analysis Exemption Threshold.** The proposed solution will create an unnecessary burden on DTSC to set a specific threshold for each chemical of concern in a listed priority product and will lead to burdensome assessments and reformulations based upon trace amounts of a chemical of concern. A reasonable *de minimis* threshold with precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union’s REACH program of 0.1% (1000 ppm) should be established.
- 4. Certified Assessors/Accreditation.** The entire program contained in Article 8 is unnecessary and should be removed.
- 5. Regulatory Duplication.** DTSC must clarify precisely when a regulated product is exempt and when it is not. Otherwise this exemption will have no utility.

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<sup>2</sup> Please refer to the Council’s previously submitted comments, which these comments incorporate by reference.

## **GENERAL COMMENTS**

### **SMALL BUSINESS IMPACTS**

As with the draft regulations, the proposed regulations do not address the significant adverse impacts that this regulation will have on small and mid-sized businesses.

The California Government Code recognizes the potential for small businesses to be adversely impacted by complex regulations promulgated by state agencies:

*The complexity and lack of clarity in many regulations put small businesses, which do not have the resources to hire experts to assist them, at a distinct disadvantage.* (California Government Code, §11340.)

In order to address this concern, the Government Code goes on to require state agencies, in developing regulations, to assess ways to ameliorate adverse impacts to small business:

*Every agency subject to this chapter shall prepare, submit to the office with the notice of the proposed action as described in Section 11346.5, and make available to the public upon request, all of the following...(5)(B) A description of reasonable alternatives to the regulation that would lessen any adverse impact on small business and the agency's reasons for rejecting those alternatives.* (California Government Code, §11346.2.)

DTSC admits in its Initial Statement of Reasons that the regulations will disproportionately impact small business. Yet despite being required to submit to the Office of Administrative Law alternatives to the regulations that would lessen the impact to small businesses, DTSC suggests no alternatives. It excuses its inaction by stating in its Economic and Fiscal Impact Statement that it cannot accurately assess impacts to businesses until *after* the regulations are actually implemented. It then claims that, even if it could assess the impacts, the underlying statute prevents it from being able to “apply these regulations in a differential manner based upon the size of a business”. In other words, the regulations are a mystery even to DTSC.

DTSC does state that it will address the disproportionate impacts, not in the regulations, but only later, in an Alternatives Analyses guidance document, which presumably would be promulgated after the regulations were final. This is insufficient process and does not comply with the dictates set forth in the Government Code.

DTSC recognizes that the impacts will be disproportionate to small businesses, and it should therefore attempt to assess those impacts and offer reasonable alternatives.

The State of California has recognized the importance of small business to the health of the economy and as a driver of job growth. It is critically important that DTSC “level the playing field” for small businesses that lack the resources of a larger company and, therefore, will have greater difficulty in complying with the regulation. As such, the Council strongly urges DTSC to develop provisions providing flexibility for small and mid-sized businesses – perhaps coordinating with the state’s Small Business Advocate or the SBA Office of Advocacy’s Regional Office – as a way to sustain and protect the viability of this important segment of California’s economy. At a minimum, DTSC must adequately explain to the Office of Administrative Law – as required by the Government Code – what alternatives are available to small businesses that will help address the adverse impacts of the regulations.

#### **REGULATIONS AS TECHNICAL BARRIER TO TRADE**

The Agreement on Technical Barriers to Trade is an international treaty administered by the World Trade Organization (WTO). The Agreement exists to ensure that technical regulations, standards, testing, and certification procedures do not create unnecessary obstacles to trade. Because the proposed regulations create a local review and reformulation process not legally applicable outside the boundaries of California, and because this process is not linked directly to safety assessments of products but is predicated upon merely speculative harm to consumers, it is not well tethered to national policy concerns and could be construed as a protectionist measure favoring California companies with access to local regulators.. Presumably, DTSC has notified WTO about these draft regulations. Notification will allow the WTO, in turn, to notify member countries of the regulation, so that they can submit official comments in accordance with the TBT agreement.

This concern is especially important as many consumer products placed into the stream of commerce in California are manufactured outside the United States, and it is likely that – unless DTSC has explicitly informed WTO of this rulemaking – most member countries of the WTO will be unaware that the public comment period in California is underway.

The Council asks DTSC to confirm publicly if and when it notified WTO about these draft regulations.

#### **SPECIFIC COMMENTS**

The Council also offers these specific comments to the individual provisions of the draft regulations:

#### **ARTICLE 1: GENERAL**

##### **§69501: Purpose and Applicability**

##### **Subparagraph (b) - PAGE 4**

## **EXEMPT OTC DRUGS**

DTSC claims that the scope of the consumer products subject to the propose regulation is “consistent with existing statutory reach” and that exempting any other consumer products “would not be in line with the intent and purpose of the authorizing legislation.” DTSC concludes that any additional exemptions beyond those set out in statute “would impermissibly shrink the scope of consumer products that are subject to the regulations.”<sup>3</sup>

We respectfully disagree. The regulations are intended to cover consumer products not already subject to a comprehensive regulatory scheme, such as with over-the-counter (OTC) drugs. By not exempting OTC drugs, DTSC risks implementing a regulatory response that would run counter to the mandates of the Federal Food and Drug Administration (FDA). Prescription drugs and medical devices are exempt from the green chemistry regulation for precisely the same reasons that OTC drugs should exempt.

Importantly, DTSC should consider that OTC drugs are subject to extensive regulation with respect to labeling and ingredients by FDA. Topical OTC’s must either conform strictly with monograph provisions regarding active content and labeling, or they must be approved individually through FDA’s pre-market drug approval process. Any attempt to alter either labeling or ingredients from approved forms would be met with a significant pre-emption risk.

Clearly, DTSC should recognize that it does not possess the jurisdictional, functional or technical expertise to regulate OTC drugs under the Federal Food, Drug and Cosmetic Act (FFDCA) and that in the United States, FDA is the sole agency responsible for determining which active ingredients are allowed for OTC use. Moreover, FDA is also responsible for evaluating the safety and efficacy of all active ingredients listed in individual OTC drug monographs and is currently evaluating the efficacy and safety of numerous active ingredients listed under several OTC tentative final monographs under a public rulemaking process which DTSC can contribute comments to.

DTSC’s inclusion of OTC drug ingredients and products under the proposed regulation would only create havoc and confusion regarding how OTC drug products and active ingredients are regulated in the United States. Moreover, this action would directly clash with the established process for determining the Generally Regarded as Safe and Effective (GRASE) status of OTC active ingredients under the FFDCA. In addition, the inclusion of new alternative OTC Drug ingredients that are not currently listed for use by FDA under an OTC drug monographs would be illegal and require FDA premarket approval under FDA’s New Drug Application (NDA) or Time and Extent process. Such inclusions generally require extensive

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<sup>3</sup> Initial Statement of Reasons, page 11.

safety, clinical and performance tests that require FDA approval, take years to conduct and cost tens of millions of dollars.

In addition, DTSC must realize that FDA OTC monographs may have different performance criteria or labeling requirements for OTC drugs used by consumers versus those used by Industrial & Institutional (I&I) facilities such as hospitals and food processing and establishment facilities. It is currently unclear whether OTC drugs targeted for human use in hospitals and food processing establishments would be subject to the proposed rule. Such establishments should also be exempted from regulation.

DTSC's inclusion of OTC drug ingredient and products under the proposed regulation would undermine FDA's OTC drug review process, potentially adversely impact public health, and, at minimum, create uncertainty with regard the marketing and availability of important non-prescription health care products in the United States.

It would be disingenuous for DTSC to argue that the "regulatory duplication" provision of the regulations will allow manufacturers of OTC drugs to make the case for being excluded from the regulation. Regulatory duplication is not even considered until the "regulatory response" stage – well after manufacturers have incurred the cost and expense of conducting an alternatives analysis and responding to the regulatory process. This would be a significant waste of time and resources.

Based on the foregoing, the Council strongly urges DTSC to exempt OTC drugs from the scope of these regulations.

#### **§69501.1: Definitions**

##### **Subparagraph (a)(19)(A)(1): "Chemical" – PAGE 8**

The definition of "chemical" contains an indirect reference to traces and precursors. It identifies not only the chemical in question, but also related chemistries – even if only distantly related – which presumes the same hazards of all loosely related chemistries with no basis for the assumption. This provision has the potential to give DTSC unlimited authority to regulate virtually any ingredient irrespective of its status as a chemical of concern. At the same time, it provides no real guidance to the manufacturer on what exactly it needs to assess. It appears to be an attempt to sweep within the ambit of the regulation everything that conceivably *might* be of interest rather than focusing agency and industry attention on the limited subset of chemicals that should be of interest, based on appropriate scientific evidence.

The Council recommends DTSC clarify and narrow the definition of "chemical". A more useful definition would be to define "chemical" as a substance or a mixture as defined by the UN GHS for these two terms.

**Substance** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

**Mixture** means a mixture or solution of two or more substances which do not react.

#### **Subparagraph (a)(38): “Legal Requirements” – PAGE 10**

The Council requests that the definition of “legal requirements” be amended to include not just product packaging, but also *labeling*.

#### **Subparagraph (a)(52): “Reliable Information” – PAGE 12**

The definition of “reliable information” should be modified to focus on the weight of scientific evidence. Single studies published in peer-review journals often conclude there exists suggestive evidence of a specific hazard however are not conclusive by themselves. It is only through evaluation of the full weight of evidence that a clear understanding of a causal relationship between exposure to a substance and an outcome of concern can be conclusively determined. It’s only through scientific debate and exchange that these conclusive results emerge. DTSC must outline how a weight of evidence approach will be followed throughout the chemical and product prioritization process as well as through evaluation of the alternatives assessment and ultimately in determining the regulatory response.

Also, much as scientific information filed with FDA may qualify as “reliable information”, so to should appropriately-vetted industry data.

#### **Subparagraph (a)(58): “Sensitive Subpopulations” – PAGE 13**

The definition of “sensitive subpopulation” refers not just to subgroups that comprise a meaningful portion of the population, but also “individuals with a history of illness” and “workers”. This is exceedingly broad and essentially makes the term so expansive as to be moot. The Council recommends deleting this reference to individuals with a history of illness (or modifying the term to conform with DTSC’s intent to cover only those “serious” or “chronic” illness affecting a meaningful portion of the population). DTSC should also delete all references to workers (whose health is regulated by Cal OSHA, as discussed later in these comments), before finalizing the regulation.

### **ARTICLE 2: CHEMICALS OF CONCERN IDENTIFICATION PROCESS**

#### **§69502.2: Chemicals of Concern Identification**

##### **Subparagraph (a)(1) and (a)(2): Initial Chemicals of Concern List**

The current “list of lists” approach is fundamentally flawed and must be changed. This is perhaps the most important and overriding problem with the proposed “process” established in the regulation.

None of the lists identified by DTSC in the proposed regulation were intended to serve as an authoritative source for this type of legislation, and each has vastly different criteria for listing a chemical. Reliance upon these lists is not a science-based approach. It offers no opportunity to remove a chemical listed elsewhere, and it flies in the face of a robust scientific process that would subject each listed chemical to exhaustive review before listing.

These lists were each compiled and reviewed for different reasons, and for different purposes, and never were these chemicals reviewed for their presence in any category of product and any resulting human exposure. Additionally, this approach virtually eliminates any opportunity to amend the list of chemicals of concern through removal of a COC as these lists have significant overlap and thus removal from only one of the lists will not remove the ingredient from the chemicals of concern list, even if evidence is presented to support its removal. This approach makes it near impossible to create a list of true chemicals of concern that meet the criteria as established by California and distracts from a focus on reducing the chemicals which have true need for reduction.

Instead, the Council recommends implementing a process that lists chemicals one at a time, allowing interested parties to submit scientific information and arguments relating to an individual chemical. DTSC could start with an initial list of chemicals with well-established hazards (say, CMRs), then gradually add to it, rather than trying to list everything at once. California already has such a process in place. The Office of Environmental Health Hazard Assessment (OEHHA), using the “authoritative bodies” mechanism under Proposition 65, notices chemicals of concern, and accepts public comment, before final listing. A similar process, which would be far more equitable, could be used with green chemistry. Note that the Prop 65 listing process, which is more rigorous, only leads to the application of warning statements on products or where they are sold. A process that compels the reformulation of products at expense to producers and with risk to consumer benefit should surely be at least as rigorous.

Based on the foregoing, the Council strongly recommends eliminating the “list of lists” approach for a more scientifically valid and defensible approach to chemical identification.

#### **Subparagraph (a)(1)(c): Endocrine Disruptors**

Particularly problematic is the inclusion of the “Category 1 endocrine disruptors” identified by the European Commission. First, it is only a “working list” in need of continued scientific rigor. The list was not created by an authoritative body and there is no conclusion on adverse impact. The list itself is

titled as "...substances for further evaluation..." further demonstrating it is not a fully vetted complete list for consideration by regulatory agencies during rulemaking and thus it should not be included in creating a list of chemicals of concern. That determination indicates doubt about whether the chemicals listed are appropriate for formal regulation.

The argument against the inclusion of the Category 1 endocrine disruptors list is further buttressed by the focus of the World Health Organization ("WHO"). WHO defines "endocrine disruption" as a material that must cause adverse effects in the intact organism, its progeny, or a sub population, and specifies what constitutes an adverse effect. The data used to generate the EU Commission list was generated using in vitro data. So by the WHO definition, the Commission data set is inadequate to establish "endocrine disruption". Thus, it's an abuse of discretion for DTSC to include this data set within its Chemicals of Concern list.

It is well known that endocrine disruption is a nascent science without strong scientific consensus. Endocrine activity is not a distinct toxicological end point per se, but rather a measure of a chemical's ability to interact with components of the endocrine system. Evidence of interaction with endocrine processes does not necessarily give rise to adverse effects.

The Council urges that endocrine disruptors be removed from the lists.

### **ARTICLE 3: CHEMICALS OF CONCERN AND CONSUMER PRODUCT PRIORITIZATION PROCESS**

As an initial matter, the Council strongly recommends that DTSC allow the use of opinions from recognized cosmetic authoritative bodies (e.g., the Cosmetic Ingredient Review<sup>4</sup>, and Scientific Committee on Consumer Safety) when identifying COCs in priority products. If a human health and safety concern is the motivation for identifying a COC in a cosmetic product, then conclusions from CIR and SCCS should necessarily be considered and possibly used to justify their inclusion or removal. In

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<sup>4</sup>The Cosmetic Ingredient Review (CIR) was formally established in 1976. All personal care product ingredients, except those reviewed by FDA (i.e., color additives, food ingredients, drug inactive ingredients), are prioritized by CIR using such factors as volume of use, structure-activity relationship, and inclusion on lists of suspect chemicals. The CIR Expert Panel, which is the decision making body of CIR, is an independent, independently-funded, panel of scientific experts with U.S. Food and Drug Administration officials and a representative of the Consumer Federation of America participating as liaison members. The Expert Panel is prohibited from direct and indirect consulting with any personal care product company, and the deliberations of the CIR Expert Panel, and all information made available to that Panel, are open to the public.

other words, if CIR makes a conclusion about an ingredient as to human safety, then that information should be viewed as authoritative and conclusive in the prioritization phase of the process.

### **§69503: General**

#### **Subparagraph (b): Information – PAGE 25**

Subparagraph (b) states that DTSC is *not limited* to using the information reviewed under 69501.4 to perform its duties of prioritizing products for regulation. This seems to undercut the focus on “reliable information” in the prior sections and removes any clear guidance gained by properly defining reliable information. If DTSC can use any information to prioritize products, as stated in this subparagraph, then any previous reference to reliable information is moot.

### **§69503.2: Priority Product Prioritization Factors**

#### **Subparagraph (a)(1)(B)(4)(b)(iii): “Worker Exposure” – PAGE 27**

Worker exposure is within the exclusive jurisdictional purview of California OSHA, which occupies the field in ensuring and addressing exposures in the workplace. This subparagraph should be deleted in its entirety, as well as any other references in the regulation to “workers” “worker exposure” or “workplace”.

### **§69503.4: Process to Evaluate Products Using Prioritization Factors**

#### **Subparagraph (e): Initial Priority Product List – PAGE 30**

Under the proposed regulation, the initial list of Priority Products shall not contain more than five products. This is a more manageable approach because it focuses attention on a limited number of products. It does not, however, limit the number of priority products that may be designated in subsequent three-year work plan cycles. Also, it does not limit the number of chemicals of concern that may be identified in a product. Additionally, it does not limit the scope of what those product categories could encompass. For example, if one of the five products was “personal care products” this would include thousands of products under one umbrella. The current proposal gives no guidance as to how the products will be classified and thus creates further ambiguity.

The Council recommends continuing to identify only a handful of priority products – no more than five – in all subsequent work plans/priority product lists.

### **§69503.5: Alternative Analysis Threshold Exemption**

Although the Council applauds the removal of the 0.01% *de minimis* level from the draft regulations, DTSC has replaced it with an Alternative Analysis “trigger” threshold that is totally discretionary to the agency, limited only by available analytical methodology. It is, therefore, subject to political pressure rather than being strictly science-based, or may be measurable only by advanced or even experimental techniques not broadly available to the regulated community. The proposed alternative analysis threshold exemption will also leave the regulated community confused as to their obligations and forcing them to incur unnecessary expense testing to detect trace levels of chemicals that have no bearing on objective safety.

Labeling this mechanism as a triggering threshold for conducting an alternatives analysis, rather than a *de minimis* level, is an attempt to avoid the reality that DTSC should comply with all other federal and international legal authorities that have set a 0.1% *de minimis*. Despite the new label, however, it is essentially a *de minimis* level. A default *de minimis* levels provides certainty and predictability to the regulated community allowing them to fully understand their compliance responsibilities. And, as such, setting a uniform threshold amount for all chemicals at 0.1% would make the proposed regulations consistent with a majority of state, federal and international regulations, including the European Union’s R.E.A.C.H. framework, which employs a 0.1% by weight *de minimis* threshold for reporting as well as the European Cosmetics Directive which includes a 0.1% *de minimis* level for over 1,300 carcinogens and reproductive toxicants.

#### **ARTICLE 4: PETITION PROCESS FOR IDENTIFICATION AND PRIORITIZATION OF CHEMICALS AND PRODUCTS**

##### **§ 69504. Applicability and Petition Contents**

Given the proposed size of the Initial Chemical of Concern list, and the potential universe of priority products (particularly in subsequent work plans), it seems unnecessary to immediately allow petitions to add to either list. DTSC should disallow any entity or member of the public to request additions to the list *until such time* as each of the initial chemicals of concern and priority products has been addressed.

The Council applauds DTSC for including a petition process that allows chemicals and priority products to be *removed* from (not just added to) the appropriate lists. However, as the only criteria right now seems to be a chemical’s presence on one of these lists, DTSC will need to provide other criteria, beyond appearance on a list, that will be considered. In addition, the petition process should extend to chemicals on the initial chemicals of concern list. Under subparagraph (b) of this section, DTSC prohibits a petitioner from removing a chemical of concern from the initial list of chemicals unless it no longer appears on any of the lists. Given our previously stated objections to the “list of lists” approach in the

first place, and particular objections to lists that are non-scientific in nature and not generated or supported by authoritative bodies this is a particularly egregious provision.

Similarly, DTSC allows entire lists of chemicals to be added as Chemicals of Concern, but not the reverse. At a minimum, DTSC should allow petitions to *remove* entire lists as well.

#### **ARTICLE 5: ALTERNATIVES ASSESSMENTS**

While the Council is pleased that timelines in the current proposal are extended relative to previous versions it is still noted that the current proposed timelines of 12 months for a Final AA report submission as well as 60 days for DTSC to review and respond to the Final AA report are much too short to satisfy the comprehensive expectations of the information included in the report. By comparison submissions of request for authorization under the EU's REACH program allow 18-24 months to prepare and submit the report followed by 12 months for the European Chemicals Agency to respond and provide opinions. Given the amount of AA reports that will ultimately be submitted under the proposal it is reasonable to believe that the Department will quickly have a large back log and will have no opportunity to adequately review and respond within the 60 day time period. Given that a lack of response is stated to not signal acceptance this will quickly leave the regulated community at a loss to proceed with selected alternatives or with priority products for which no alternative was selected while awaiting feedback from DTSC.

#### **§69505.4: Alternative Assessments: Second Stage Subparagraph (A)(2)(C): Economic impacts – PAGE 43**

This provision requires the responsible entity to take into account all “projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered”. This is far too broad and complex an undertaking for almost any business, as most would be hard pressed to even provide estimates for all the factors involved. More importantly, there is insufficient agreement on the methodologies and scope to be used to deliver useful, reproducible results – and even those results will only be estimates.

#### **ARTICLE 6: REGULATORY RESPONSES**

#### **§ 69506.7(b): Engineered Safety Measures or Administrative Controls**

Under this provision, subparagraph (b) gives DTSC the authority to “integrally contain” a chemical of concern in a product. In other words, DTSC has the power to *redesign* a product and/or manufacturing process if it feels it is necessary to “enclose the hazard posed by the chemical of concern”. This is wholly

unacceptable. DTSC does not have the expertise to redesign personal care products, nor any of the thousands of other products in the marketplace.

Moreover, this subparagraph is completely unnecessary in light of the other regulatory responses that DTSC has provided itself, such as chemical restrictions and product prohibitions. As such, the Council requests that this subparagraph be delete in its entirety.

**§ 69506.11(b): Regulatory Duplication**

Assessing the scope of other laws that could potentially cover the product or chemical of concern, and whether they address the same concerns covered by the DTSC regulations, is the type of analysis that should be used in the initial stages of the regulatory process to determine whether the product or chemical should be regulated at all. Relegating this determination to the “regulatory response” stage of the process is inconsistent with the language prohibiting regulatory duplication and a waste of resources by DTSC and the regulated community.

To be sure, the Council supports the inclusion of a “regulatory duplication” provision that exempts consumer products already regulated by one or more federal or State of California regulatory programs, or international trade agreements, providing equivalent or greater protection of public health or the environment. For example, it is well understood that personal care products are comprehensively assessed for human health concerns and regulated by the U.S. Food and Drug Administration (FDA). Consequently, if a chemical-product combination is identified by DTSC *solely* because of questions on human health, and the product is a personal care product, there would be “regulatory duplication” with FDA and that product therefore would be exempt from these regulations.

Finally, the Council would also recommend amending the draft regulations to state that, where a federal or state agency has the *authority to regulate* (even if DTSC believes the extent to which this authority is exercised to be inadequate), this should be sufficient to justify an exemption. It is not for DTSC to judge if another agency is properly regulating a product, but only to understand if there exists regulatory duplication. If an exemption is provided for in these cases, and DTSC decides to regulate, it could potentially lead to overlapping regulations by different authorities, particularly if the other agency decides to regulate at some time in the future. This will result in confusion for the regulated community.

The Council strongly supports regulatory duplication to be considered early during the prioritization process and recognition that chemical-product combinations under consideration for human health

concerns in personal care products should be exempt from the AA process due to the fact that the products are already adequately regulated for human health by the FDA.

#### **ARTICLE 8: ACCREDITATION BODIES AND CERTIFIED ASSESSORS**

The entirety of Article 8 is unnecessary to the efficient implementation of the statute and should be eliminated.

DTSC justifies its decision to include this provision by stating in its Initial Statement of Reasons:

*By doing nothing or adopting the regulations without a certification process, DTSC would be required to conduct its outreach and training on AA through existing applicable and relevant mechanisms such as factsheets, mailers and workshops. Adoption of these regulations without including a certification process for assessors would:*

- *increase the amount of time required for DTSC's reviews of the work that is submitted;*
- *result in a lack of educational requirements and any person could prepare an AA;*
- *result in there being no mechanism to widely disseminate advancements in technologies and manufacturing practices; and*
- *result in a lack of consistency in quality and rigor in the preparation of AA.*

Unfortunately, this reasoning is flawed. First, DTSC is publishing an alternatives analysis guidance document following the promulgation of these regulations. There is no need for mailers and factsheets once the guidance is completed. Likewise, DTSC will be able to determine rather easily whether a responsible entity has complied with the process identified in the guidance, without the need for a certified assessor.

In addition, DTSC has a host of regulatory responses at its disposal to ensure that alternative analyses are properly conducted, and that responsible entities are sufficiently motivated to comply. There is no need for DTSC to add another layer of bureaucratic oversight to its green chemistry program.

Consider the problems raised by the proposed accreditation and certified assessor program. For example, how will it handle concerns with trade secret protection and confidential business information? There is no discussion of how trade secrets or confidential business information will be treated by certified assessors or accreditation bodies, which are not covered under Article 10 (which only applies to submissions to DTSC). Likewise, the criteria for becoming a certified assessor is so extensive that most people – even those with years of education and experience in conducting alternative analyses – would not qualify, severely hampering businesses hoping to use internal resources to meet this requirement.

Ms. Krysia Von Burg  
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For these and other reasons, the Council believes Article 8 should be deleted in its entirety. Otherwise, at a minimum, DTSC should clarify that the role of a certified assessor is merely to attest to conformance with the AA report format.

## **CONCLUSION**

While the proposed regulations may ultimately provide some benefit to public health and the environment, they also create regulatory inconsistencies and impose unnecessary costs upon industry. We appreciate that DTSC faces a statutory deadline for issuing these regulations, but we believe that it is critical that DTSC construct a program that is workable from the onset, with a narrowly drawn scope and requirements that are not cost-prohibitive.

To that end, the Council urges you to consider our comments to avoid creating barriers to innovation, detrimentally impacting the California and U.S. economy, and ultimately failing to improve protection of public health and the environment.

Sincerely,

Thomas F. Myers  
Associate General Counsel

**TATRO TEKOSKY SADWICK LLP**  
ATTORNEYS AT LAW

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October 11, 2012

*Via E-mail and U.S. Mail*

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

Re: Comments on Revised Text of the Regulations for  
Safer Consumer Product Alternatives

Dear Ms. Von Burg:

This letter submits Pharmavite LLC's comments on the latest text of the Proposed Regulations for Safer Consumer Product Alternatives. Pharmavite is one of the nation's leading dietary supplement manufacturers. As the latest version of the proposed regulations does not address, modify or resolve the issues, points and concerns raised by Pharmavite's previously-submitted comments regarding these regulations, Pharmavite submits the following comments to supplement, but not to supersede, Pharmavite's previously-submitted comments. Pharmavite requests that the current text be revised to address these comments and resolve Pharmavite's concern in a manner consistent with Pharmavite's position as expressed below.

The proposed regulations are intended to create a systematic, science-based approach to identify, evaluate, prioritize and regulate chemicals or chemical ingredients in consumer products. These are laudable goals and Pharmavite supports using a science-based approach for these complicated issues.

Pharmavite writes at the specific invitation of DTSC in connection with the scope of the exemption of “food” from the definition of “consumer product.” Pharmavite has reviewed the governing statutes, the draft regulations, the revised text of the draft regulations, DTSC’s explanatory information and documents, and comments submitted by the regulated community throughout this regulatory process. It generally appears in the proposed regulations’ explanatory documents and information, as well as from general DTSC commentary, that the regulations exempt food and do not seek to “capture” food within this regulatory program. This general intent to exempt notwithstanding, Pharmavite is concerned that these draft regulations may contain an overly narrow definition of the term “food” which creates a possible ambiguity about whether food ingredients are included within the food exemption. A clarification is needed to state expressly that the exemption for food includes both the finished food product and its individual ingredients. Pharmavite requests that the proposed regulations make clear that both food and food ingredients are exempt from the definition of “consumer product.”

Without the clarification Pharmavite seeks, there could be confusion as to whether the consumer product exemption is limited to food as a finished product and does not extend to food ingredients (components). For example, without the requested clarification, it might be asserted that orange juice intended to be incorporated as an ingredient in an orange flavored or juice-containing frozen food product would not be exempt while the same orange juice would be exempt if it were intended to be consumed as a beverage. The clarification Pharmavite seeks makes sense as under California as well as Federal law food ingredients (including dietary supplement ingredients) are defined as food.<sup>1</sup> We hope that these comments and suggestions provide an approach for resolving the potential and apparently inadvertent “capture” of food ingredients in the definition of “consumer product.” Accordingly, Pharmavite respectfully requests that draft § 69501(b) be revised to eliminate this potential confusion and to state explicitly that food as well as its ingredients are not consumer products for purposes of these regulations.<sup>2</sup>

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<sup>1</sup> Pharmavite’s dietary supplement products, as well as their ingredients, are defined as food pursuant to both federal law (21 United States Code § 321(ff)) and state law (17 California Code of Regulations § 10200(b)). The federal program thoroughly and comprehensively regulates the safety of food and food components/ingredients. The FDA system is consistent with the purposes and goals of the proposed DTSC regulations, addressing the area fully and adequately. Adoption of the exemption for food components/ingredients avoids inconsistencies with applicable federal and California regulatory systems; it avoids a result that would be contrary to California Health & Safety Code § 25257.1(c); and it furthers the purpose of the state legislation.

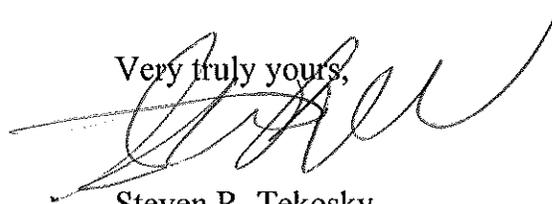
<sup>2</sup> Pharmavite does not want to duplicate the comments of others, and as there have already been substantial comments submitted on the issue of food packaging, Pharmavite merely wishes to state that it, too, believes that food packaging should be exempt from the definition of consumer product.

Ms. Krysia Von Burg  
October 11, 2012  
Page 3

**TATRO TEKOSKY SADWICK LLP**  
ATTORNEYS AT LAW

We appreciate the opportunity to assist your efforts to draft workable and appropriate science-based regulations and at the same time avoid a potential and apparently inadvertent “capture” of food ingredients in the definition of “consumer product.”

Very truly yours,

A handwritten signature in black ink, appearing to read 'S. Tekosky', written over a horizontal line.

Steven R. Tekosky

## GCREgs@DTSC

---

**From:** Yvonne Pierce <yvonnep373@comcast.net>  
**Sent:** Monday, October 01, 2012 5:43 PM  
**To:** GCREgs@DTSC  
**Subject:** State Chemical Disclosure Regulation

As a concerned grandmother, I urge the Department of Toxic Substances Control to resist lobbying efforts from the chemical industry and do what's right for future generations. I'm appalled that we have fallen behind Japan, Canada, and European nations in this regard.

Yvonne Pierce  
Corte Madera, CA



## Plastic Pipe and Fittings Association

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Phone: 630/858-6540 • Fax: 630/790-3095 • [www.ppfahome.org](http://www.ppfahome.org)

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

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

Oct 11<sup>th</sup>, 2012

The Plastic Pipe and Fittings Association (PPFA) would like to thank the DTSC for the opportunity to comment on the California DTSC proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code.

PPFA is concerned that the complexity, scope and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to products that pose risks of harm and promoting innovation.

PPFA understands that many in the industry have input considerable effort to suggest meaningful, practical and legally defensible regulatory alternatives, and that the current proposal still demonstrates limited progress, and represents unscientific and over burdensome regulation.

Any state regulatory Green Chemistry program must contain a strong objective and scientific foundation in order to credibly inform choices made by consumers and other participants in the value chain. These foundations should not be material lists, but Life Cycle Analysis.

Although DTSC has estimated that some 1,200 substances will be covered by the regulation, the ACC estimates that the regulation would affect at least 4,000, if not more. This would strain both industry and the State of California.

PPFA is also concerned that the proposed SCP regulation will cause unwarranted concern and worry in the State's population, and potentially beyond to even include other States. How will citizens interpret that a thousand of the most commercially important substances are designated as subjects of the state's "concern," based only on a loose assessment of hazard characteristics gleaned from lists compiled by non-State entities?

In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer

products. More to the point, consumer apprehension will certainly lead to deselection – and for all the wrong reasons.

Because it identifies “chemicals of concern” and lacks a clear, scientific process for determining which chemicals and products would or could be selected for regulation, manufacturers and retailers would be left to guess at what would constitute a “safe” product or how to remain in compliance with the regulations. This kind of uncertainty is a massive disincentive to the development of better or safer products.

For example, if “safer” consumer products were to be chosen based on this method, using chemicals and material lists alone, this regulation could incorrectly recommend (and could force) the use of the worst in class products.

This materials list approach would seem to support the use of 100 year old Edison (incandescent) light bulbs. These Edison light bulbs seem to consist of only copper, aluminum and glass. It would seem this draft regulation would prefer the Edison bulb over all of the better (and likely future) lighting technologies – such as fluorescent, halogen, LED, and so on. This would pollute the environment, impact the air and water quality of California and waste more energy to satisfy an incorrect decision making regulation.

PPFA asks the DTSC to come back and propose a much simpler program based on LCA and abandon the incorrect pathway of materials and chemical lists for deselection of products.



October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

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

Subject: Safer Consumer Product (SCP) Alternatives Proposed Regulation

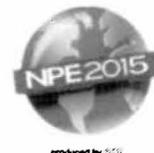
Dear Ms. Von Burg:

SPI: The Plastics Industry Trade Association respectfully submits the following comments on California's Safer Consumer Product Alternatives proposed regulation, published on July 27, 2012.

SPI represents the third largest manufacturing industry in the United States, accounting for more than \$380 billion in annual shipments. In California, more than 2.4 million jobs are directly and indirectly tied to the plastics industry. The average wage of an industry employee is greater than \$41,000, excluding benefits. The industry's direct payroll including captive products is \$3 billion with dependent industries adding another \$94 billion to the state's payroll. Products of the plastics industry are utilized in almost every sector of the economy including agriculture, aerospace, automotive, electronics, medical, transportation, construction, packaging, recreation and sports and more.

We appreciate the considerable effort the Department of Toxic Substances Control (DTSC) has invested to develop the proposed rule and acknowledge the progress that has been made since the draft regulations were first released in 2010. Despite this effort, there remain outstanding issues for the regulated community that stakeholders have previously communicated to you throughout this process.

The regulations do not include a clear or science-based process by which the DTSC will select chemicals and products it regulates, resulting in great uncertainty for the regulated community. The proposal falls short in being science-based in a number of respects: identifying chemicals of concern through a merger of lists; and, in proposing a narrative, not a scientific standard and process for identifying priority products. Furthermore, we believe that the prioritization and evaluation process must be based on



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exposure and hazard. The wording of the proposal is such that the substitution of a compound not fully proven or subject to a rigorous safety evaluation runs the great risk of creating unintended consequences that could adversely impact the health of consumers, particularly the young, elderly and immuno-compromised, as well as the environment and the regulated community.

The proposal seeks to establish an all-encompassing program in which virtually all commercially available products and their packaging will be subject to the regulation and not simply common everyday consumer products. Full implementation of the rule as proposed would create a costly new government program requiring substantial resources. With competing budget priorities of the state, currently and going forward, the sustainability of this program remains highly questionable.

The regulations are written in a way that gives the department near-limitless discretion over a process that will be used to regulate consumer products. Compliance with the regulation will be a challenge for all entities as it appears to be an ever-shifting target. DTSC retains so much discretionary authority that it virtually eliminates any certainty that a business might have in terms of regulatory treatment.

The intent of the underlying statute, AB 1879 (Feuer-2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to promote the innovation of safer consumer products. However, the proposal continues to threaten businesses' intellectual property which is the basis for innovation.

The statute is clear on the matter of regulatory duplication, stating that it does not authorize the department to supersede the authority of other agencies and directing that the department shall not duplicate or adopt conflicting regulations for products already regulated or subject to pending regulation. The proposal goes beyond the statute. In referencing the Economic and Fiscal Impact Statement Form 399 accompanying the proposal, the state speaks narrowly to the regulatory authority of the U.S. Environmental Protection Agency, while remaining silent on the role and responsibility of the U.S. Food and Drug Administration (FDA) and the U.S. Occupational Safety and Health Administration (OSHA), among others. Yet the state proposes to duplicate those federal regulatory responsibilities under its proposal. For example, food contact materials are already fully regulated by the FDA. Further regulation of these materials by DTSC would be in direct conflict with the existing federal regulatory scheme. Including food contact materials within the scope of the proposal is duplicative, costly and may impede industry's development of new materials that can improve the safety, quality and availability of food products.

The requirement for an end-of-life program as called for in the proposal is excessive. Provisions are unnecessary, questionable and duplicative of responsibilities of other state agencies. The provisions

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SPI Comments to SCP Proposed Regulations  
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cross jurisdictional boundaries and impose DTSC oversight on issues of solid waste management already under the authority of other state agencies, such as the Department of Resources Recycling and Recovery. These provisions expand DTSC's charter in an unnecessary manner, resulting in further costs to the state and regulated community.

Again, we recognize and appreciate the efforts put forth by the department, but we strongly encourage DTSC to continue to work with the regulated community of stakeholders to finalize a workable, practical and defensible proposal.

Should you have any questions or comments, you may contact me at: [jadams@plasticsindustry.org](mailto:jadams@plasticsindustry.org).

Sincerely,



Jane A. Adams  
Senior Director, State Government Affairs

cc:

The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business and Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor



October 11, 2012

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

Subject: TITLE 22, California Code of Regulations; 45-DAY PUBLIC NOTICE AND COMMENT PERIOD SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2011-02  
Office of Administrative Law Notice File Number: Z-2012-0717-04

E-mail Address: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

Dear Ms. Von Burg:

On behalf of Plumbing Manufacturers International (PMI), we are submitting the following comments in response to the 45-day public notice and comment period for the California Safer Consumer Product Alternatives Act regulation.

PMI is the leading national and technical trade association of plumbing products manufacturers in the United States. Our 32 manufacturers and allied members include many of the well-known companies selling plumbing products in the United States for decades. Our collective group of manufacturers is responsible for at least 90% of all the fixtures and fittings sold in the U.S. market including California.

PMI is a strong advocate for the efficient and safe use of water, a commitment that is evident in our longstanding partnerships with the US Environmental Protection Agency's (EPA) WaterSense Program and with organizations such as the Alliance for Water Efficiency. We also advocate for public health and safety and product performance, as well as the harmonization of the requirements of plumbing codes and standards.

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the considerable effort the Department of Toxic Substances Control [DTSC] has once again invested in its latest effort to develop an efficient and effective regulatory system.

We are pleased that the Department has opted to focus the program initially by only identifying up to five Priority Products. This is a practical approach that will enable the Department to pilot this unique program and to learn what works and does not work and make adjustments accordingly. Unfortunately, DTSC is proposing a regulatory scheme far in excess of that which it needs to conduct the initial phase and far in excess of that which its own resources can support. We, in concurrence with GCA, strongly recommend DTSC consider a more

focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on hazard, exposure and the likelihood of harm. We believe that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft. We remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

One of the most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.

It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.

Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.

The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on **exposure** and **hazard**, and it must avoid duplication and conflicting regulatory requirements.

- DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as its starting point. Upon removal of statutorily exempt chemicals and duplicates, the department predicts a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
- GCA supports this two step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying its list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer

products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.

The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

In conclusion, PMI feels it is important that the process be revised to one that is workable and achievable with regard to the scope, the prioritization of products, the prioritization of chemicals, the alternative analysis, and the reporting requirements. We would urge the DTSC to fully endorse and adopt PMI's comments and requests for guidance for the Safer Consumer Product Alternatives Act regulation and move to ensure the logical, efficient and transparent implementation of the Act.

Sincerely,



**Len Swatkowski**

Technical Director

Plumbing Manufacturers International

1921-G Rohlwing Road

Rolling Meadows, IL 60008

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cc: The Honorable Matt Rodriguez, Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Miriam Ingenito, Deputy Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Kristin Stauffacher, Assistant Secretary, CalEPA [cepacomm@calepa.ca.gov](mailto:cepacomm@calepa.ca.gov)

Nancy McFadden, Cabinet Secretary, Office of the Governor [nancy.mcfadden@gov.ca.gov](mailto:nancy.mcfadden@gov.ca.gov)

Mike Rossi, Senior Business & Economic Advisor, Office of the Governor [mike.rossi@gov.ca.gov](mailto:mike.rossi@gov.ca.gov)

Cliff Rechtschaffen, Senior Advisor, Office of the Governor [cliff.rechtschaffen@gov.ca.gov](mailto:cliff.rechtschaffen@gov.ca.gov)

Martha Guzman-Aceves, Deputy Legislative Affairs Secretary, Office of the Governor [martha.guzman-aceves@gov.ca.gov](mailto:martha.guzman-aceves@gov.ca.gov)

Barbara C Higgins, Executive Director, PMI

Jerry Desmond Jr., Desmond & Desmond. PMI Legislative Advocate

American Standard Brands, Inc. \* Amerikam, Inc. \* Bradley Corporation \* BrassCraft Mfg. Co. \* Chase Brass & Copper Company \* CSA International \* Delta Faucet Company \* Dornbracht Americas \* Duravit USA \* Elkay Manufacturing Company \* Fisher Manufacturing Company \* Fluidmaster, Inc. \* Gerber/Danze Plumbing Fixtures LLC \* Hansgrohe, Inc. \* IAPMO \* InSinkErator \* Kohler Company \* KWC America, Inc. \* Lavelle Industries \* LSP Products \* Moen Incorporated \* Mueller Brass Company \* NEOPERL, Inc. \* Pfister \* Sloan Valve Company \* Speakman Company \* Symmons Industries Inc. \* T & S Brass and Bronze Works, Inc. \* TOTO USA \* VitrA USA \* Water Pik \* WCM Industries, Inc.



## Camie-Campbell, Inc.

9225 Watson Industrial Park St. Louis, MO 63126  
800-325-9572 314-968-3222 FAX: 314-968-0741 [www.camie.com](http://www.camie.com)

September 14, 2012

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

### **Re: PLZ Aerospace Corporation Comments on Safer Consumer Products Draft Regulation (July 2012)**

Dear Ms. Von Burg:

On behalf of PLZ Aerospace, I respectfully submit the following comments regarding the Department of Toxic Substances Control's draft Safer Consumer Products Regulation dated July 27<sup>th</sup>, 2012.

PLZ Corporation has acquired seven specialty chemical companies that all have been in the industry for many years. They are Claire Products, Sprayway, CPC, Camie, K-G Spray Pak and Assured Packaging. Our product lines service the I&I market, Industrial and some retail. We manufacture aerosol adhesives, lubricants, cleaners, air fresheners, automotive products and other specialty products. We have manufacturing facilities in Missouri and in Canada and employ over 500 people.

I appreciate the opportunity to provide comments on such an important issue. I would like to start by noting that my company appreciates the reduced number of chemicals that will make up the initial Chemical of Concern list. This is more realistic and will make it easier for industry to determine the impact of the green chemistry program on products sold in California. I would also like to thank the department for the process it has used to allow for extensive input from all stakeholders.

My company, however, continues to have concerns with many aspects of the regulations and the impact the program will have on our company and products. Although PLZ has a large work force, our R&D staff is small and seems to spend most of its time formulating for regulatory compliance. The margins in this industry do not allow us to increase our R&D budget. One of our largest concerns is being able to respond to the increase in workload related to this regulation. We appreciate the fact that you will address only 5 Priority products at a time, however, this may equate to



California VOC Compliant Products



Chemical Specialty Products



Earth-Friendly Biodegradable Products



## Camie-Campbell, Inc.

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many formulas for each product for us. We still feel that this may be more than industry can handle, depending on the complexity of the formulas.

The deadlines that are included in the regulation will also be a major concern for us. We feel that we will need more than 60 days for Priority Product Notification and more time for the preliminary and final Alternative Analysis Report. This is especially true for our adhesive and coatings formulas which have many formulation limitations due to compatibility and performance requirements.

Another issue that is especially troubling for our adhesive products in particular is the issue of trade secret formulas. The solids composition of our products is proprietary and is what allows us to maintain market share. If that information is made public it will allow our competitors to easily duplicate our products.

Specialty chemical products improve the quality of life for most Californians. Our product offerings allow consumers to maintain and improve their possessions. The PLZ Corporation is proud to conduct business in the state of California, but it must be noted that it is becoming increasingly difficult to do so. If this regulation were approved as currently drafted, the company will be faced with uncertainty, fiscal hurdles and less opportunity for innovation. PLZ hopes that providing these comments will help advance efforts to create a practical, scientifically-based, and legally defensible regulation.

Respectfully,

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California VOC Compliant Products



Chemical Specialty Products



Earth-Friendly Biodegradable Products



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October 11, 2012

Ms. Krysia Von Burg  
Safer Consumer Product Alternatives Regulation Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 27, 2012)**

Dear Ms. Von Burg:

The Procter & Gamble Company (P&G)<sup>1</sup> appreciates this opportunity to comment on the proposed Safer Consumer Product Alternatives Regulation<sup>2</sup> (“proposed regulation”) released on July 27, 2012, by the California Department of Toxic Substances Control (“DTSC” or “Department”) for the implementation of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008).

**General Comments**

P&G continues to fully support what we believe was the original vision for California’s inception and development of the Green Chemistry Initiative; that is, to create the opportunity and incentives to accelerate and promote sustainable innovation while making meaningful improvements in the protection of the environment and health of California consumers and their children. We recognize the considerable effort DTSC has once again invested in this latest effort to develop an effective regulatory system to implement the Green Chemistry Initiative in the state.

Director Raphael has often described her vision for creating a regulatory program to implement the Green Chemistry Initiative that is “practical, meaningful and legally defensible.” We see evidence of this vision in the Department’s decision to initially focus implementation of the program on an identified small collection of (up to five) Priority Products. This is a practical approach that will enable the Department to pilot this unique

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<sup>1</sup> The Procter & Gamble Company is the world’s leading consumer products company operating in more than 80 countries worldwide. Our strong portfolio of recognized, quality and leadership brands includes numerous household, industrial and personal care products. Procter & Gamble is fully committed to helping solve sustainability challenges, which is embedded in our Company Purpose “to improve the lives of the world’s consumers, now and for generations to come.” Please visit <http://www.pg.com> for the latest news and in-depth information about P&G and its brands.

<sup>2</sup> <http://www.dtsc.ca.gov/upload/SCPPProposedRegulationsNoUnderlineJuly2012.pdf>

program, to learn over time and to make adjustments according to what works and what does not work. The practicality of this promising start unfortunately becomes lost with the ensuing, complex regulatory scheme that far exceeds that which is needed in the conduct of an initial phase and generates paperwork and program administration duties far in excess of what DTSC resources can support.

### **Primary Concern**

The clear persuasion in the proposed regulation for substitution with a “safer” alternative as an outcome of the Alternatives Assessment (AA) process fails to appropriately recognize and implement the more holistic, risk-based approach outlined in AB 1879. The statute requires an evaluation of potential hazards and critical exposure pathways to determine the right course of action to reduce risk. One possible action identified in the statute is “no action,” which is an indication that DTSC must consider the overall safety of a Priority Product – with no change – as an equally potential outcome as substitution with an alternative. Unfortunately, DTSC has distanced the Safer Consumer Product Alternatives Regulation from the clear direction provided in AB 1879 and has developed a proposed regulation that favors replacement of Chemicals of Concern with less hazardous alternatives (to the maximum extent feasible) over a more holistic, risk-based approach. P&G strongly asserts that a risk-based evaluation of Chemicals of Concern in Priority Products is the solution that will deliver meaningful and measurable improvements in public health and environmental protection. DTSC’s continued focus on minimizing hazard will miss the opportunity for game-changing, sustainable innovations that deliver significant environmental benefits and realize the original vision of the Green Chemistry Initiative for California.

P&G has expended significant resources over the last five years sharing our scientific expertise in consumer product safety and alternatives analysis with DTSC -- from the genesis of the Green Chemistry Initiative, through the legislative enrollment of AB 1879 and SB 509 and the numerous informal draft regulations, by George Daston’s participation on the Green Ribbon Science Panel and lectures by our top scientists at DTSC symposia, to engagement in the current formal rulemaking process. Throughout this entire journey, we’ve demonstrated the significant attention to product safety that we, and other leading industry partners, apply to our trusted brands. Green Chemistry thinking has shaped our ingredient choices from the very start of the product design process for decades. At P&G, we were evaluating life cycle impacts of our products to identify opportunity areas long before “life cycle analysis” became a recognized practice in the industry. We’ve freely shared with DTSC our science, expertise and learnings collected through trial, error and discovery to help shape the implementation of the Green Chemistry Initiative. Our commitment to this effort grew from a core belief that, if implemented correctly, this program would firmly position California (and the United States) as a global leader of sustainable innovation and evolved chemical management.

We believe that a very different outcome will emerge from implementation of the current proposed regulation than the optimistic vision from which this journey began. Instead of California leading the world as the entrepreneurial birthplace of sustainable innovation, the state will likely trail other geographies in the competitive global marketplace due to the slow emergence of technology that can successfully navigate the

complex regulatory environment. Further, the economic impact this regulation will have on California businesses and manufacturers who sell to California consumers is uncertain because of its broad scope and untested provisions; however, an independent analysis by the California Foundation for Commerce and Education (CFCE) predicts total net costs to California businesses and consumers to approach \$150 billion in the first 25 years of implementation.<sup>3</sup> These dire predictions for California during this period of slow economic recovery sharply contrast with the original promise of the California Green Chemistry Initiative and leave the regulated community questioning the purpose and effectiveness of the command-and-control regulatory proposal before us now.

### **Recommendation**

P&G is a member of, and active participant in, the Green Chemistry Alliance (GCA), a group of major trade associations and companies that represent numerous broad industrial sectors in California. We support the written comments of the Green Chemistry Alliance, as well as those of our individual Industry trade associations, including the American Chemistry Council (ACC), the American Cleaning Institute (ACI), the Consumer Specialty Products Association (CSPA), the Grocery Manufacturers Association (GMA) and the Personal Care Products Council (PCPC). We join the voices of these organizations and the numerous member companies that comprise them in our recommendation to DTSC to revise the direction of the proposed regulation to fully achieve Director Raphael's vision of a "practical, meaningful and legally defensible" program. We strongly recommend that DTSC consider the following points to guide further refinement of the regulation:

- Implement a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on a risk-based evaluation of hazard, exposure and the likelihood of harm. This approach will deliver the **meaningful** results of Director Raphael's vision by achieving measureable improvements in public health and environmental benefit. The risk-based approach will focus DTSC's limited resources on opportunity areas and yield the best overall outcome for California in terms of meaningful results and economic impact.
- Develop appropriate criteria to identify Chemicals of Concern and a risk-based process that evaluates both exposure and hazard to prioritize Chemicals of Concern and the Priority Products in which they are present. This is a critically important improvement needed in the regulation to address the statutory requirement for such a process and to improve transparency of the program for the regulated community and interested stakeholders. DTSC's attention to this starting point of the program is necessary to strengthen and align the proposed regulation with a second component of Director Raphael's vision, which is to ensure the Safer Consumer Product Alternatives Regulation is **legally defensible**. Furthermore, the proposed regulation threatens vital intellectual property upon which US innovation is based, requiring submission of information that is unnecessary and far in excess of the substantiation required for protection of confidential business information under the

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<sup>3</sup> <http://www.calchamber.com/Headlines/Pages/10082012-NewConsumerProductRulesFailtheTestofGoodEconomics.aspx>

California Uniform Trade Secrets Act “UTSA” (Civil Code sections 3426.1-3426.11). The broad discretion afforded to the Department in the proposed regulation to make a decision about a trade secret claim is inconsistent with California state law. This inconsistency again raises a question of the legal defensibility of the proposed regulation. The importance of trade secret protection to a functioning, competitive marketplace cannot be overstated. We implore DTSC to tighten the trade secret provisions of Article 10 (consistent with UTSA) and preserve a competitive environment in which sustainable innovation fuels the California economy.

- Simplify and focus the regulation to address the third component of Director Raphael’s vision. The overly broad scope and complexity of the proposed regulation raises numerous *practical* problems. For example, a starting collection of approximately 4,000 discrete Chemicals of Concern comprised by the identified 22 lists of hazardous chemical substances and chemical classes, and the lack of a clear prioritization process for Chemicals of Concern in Priority Products, provide no guidance to the regulated community as to where to anticipate regulatory compliance effort. An unknown *de minimis* threshold for all possible presence of a Chemical of Concern in a Priority Product (including intentional addition as an ingredient and mere presence at trace levels as a contaminant) provides no upfront regulatory certainty if a manufacturer or their recognized brand is within scope of the reporting, alternative analysis and supply chain communication obligations discussed in the proposed regulation. This uncertainty facing the regulated community; the sheer workload awaiting DTSC staff when the regulatory submissions begin; and the expected economic impacts that will reverberate throughout industry as a result of compliance activities and loss of trade secret information collectively scream that this proposed regulation is far from practical.

We respectfully submit the attached, detailed comments to address the provisions of the proposed regulation that require attention prior to issuance of a final rule. These provisions are critical to establish a practical, meaningful and legally defensible regulatory framework and have been developed through the collective expertise of our industry trade associations and the membership of the Green Chemistry Alliance.

P&G remains committed to working collaboratively with DTSC, industry partners and other key stakeholders to develop a workable regulatory framework to achieve the promise and vision of the Green Chemistry Initiative. We agree with Director Raphael that an emphasis on practicality, legal defensibility and successful achievement of meaningful and measureable improvements in public health and environmental protection is undoubtedly the right goal and mission for this rulemaking process. We strongly encourage DTSC to carefully review and consider the comments and recommendations presented by the regulated community to make the right decisions in this rulemaking process for California’s consumers, the state’s natural environment, the state’s economy and the future of sustainable innovation in the United States. The proposed Safer Consumer Product Alternatives Regulation will be the landmark framework against which other U.S. states and geographies model; we entreat the Department to undertake this responsibility thoughtfully and with full

consideration of the expected economic impact and implications for innovation flexibility of the consumer product industry.

Should you have any questions about these comments, please contact me directly at (513) 983-2531 or [froelicher.jm@pg.com](mailto:froelicher.jm@pg.com) or contact Beth Percynski in P&G's Sacramento office at (916) 442-3135 or [percynski.ba@pg.com](mailto:percynski.ba@pg.com).

Sincerely,

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## Detailed Comments on the Proposed Safer Consumer Product Alternatives Regulation The Procter & Gamble Company

### Overarching Issues

**Regulatory Duplication.** It is essential that the proposed regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently reviewed in the US. The foundational question upon which identification and prioritization of Chemicals of Concern/Priority Products must commence is whether another agency already regulates the potential health or environmental impact from the Chemical of Concern in the subject product. An affirmative answer to this question prohibits the Department from any further action because of regulatory duplication, which is prohibited by the statute. For example, it is well understood that personal care products are comprehensively assessed for human health concerns and regulated by the U.S. Food and Drug Administration (FDA). Consequently, if a chemical-product combination is identified by DTSC *solely* because of questions on human health, and the product is a personal care product, there would be “regulatory duplication” with FDA and that product would be exempt from the regulation.

The proposed regulation gives the Department the discretion to determine the adequacy of the regulatory requirements currently in place as they compare to the breadth of the Safer Consumer Product Alternatives Regulation’s governance. The Legislature did not intend this discretion, as evidenced by the language of SB 509 (Simitian, 2008). This is an example of regulatory overreach by suggesting that the Department should make a hypothetical decision about the impact of its own regulation compared to the impact of other regulations. The Department has no authority to pass judgment on the sufficiency of current regulatory authority and implementation. The statute under SB 509 (Simitian, 2008; Health & Safety Code §25257.1(b) and (c)) is clear on the matter, with two applicable provisions:

*(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency.*

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

The proposed regulation goes beyond the statute by asserting the Department’s authority to provide a level of public health and environmental protection for a Priority Product that is equivalent to or greater than the protection provided by other agencies under other regulatory constructs.

Furthermore, there are limited, if any, benefits from the proposed regulation considering the current federal oversight of consumer product safety. The U.S. Environmental Protection Agency (EPA) administers the Toxic Substances Control Act (TSCA) to regulate chemical ingredients in consumer products and prevent those substances that present an unreasonable risk of injury or illness to human health or the environment from commercialization in the U.S. The Consumer Product Safety Commission (CPSC) administers the Federal

Hazardous Substances Act (FHSA) and other statutes that protect the public from unreasonable risk of injury or illness during the use of consumer products. Likewise, federal law prohibits the marketing of adulterated cosmetics that contain any poisonous or deleterious substance that may render them injurious under the Federal Food, Drug and Cosmetics Act. In addition to these national, uniform standards, consumer product manufacturers already have strong product stewardship programs and market incentives to ensure that their products are safe and effective. The proposed regulation seeks to replace these existing protections with local government mandates and disrupt the natural order of a free market economy by authorizing DTSC to supplant the purchasing choice of California consumers and dictate whether or not products – *including safe products* – can be marketed in California.

Finally, P&G fully supports the request made by the Personal Care Products Council in their written comments to remove Over-The-Counter (OTC) drugs from the scope of the regulation. DTSC regulation of OTC drugs is unnecessary because of the extensive existing oversight by the Federal Food and Drug Administration (FDA) with respect to OTC drug labeling and product ingredients. For example, topical OTCs must either conform strictly to monograph provisions regarding active content and labeling, or they must be approved individually through FDA's pre-market drug approval process. Any attempt by DTSC to implement a regulatory response that would run counter to the FDA mandates for either labeling or ingredients would face a significant pre-emption risk. The proposed regulation exempts prescription drugs and medical devices for precisely the same reasons that DTSC should exempt OTC drugs from the scope of this regulation.

**Science-based Processes.** To build confidence in the Green Chemistry Program, DTSC needs to operate the program with a rigorous, science-based approach, in concert with state, federal and international best practices. DTSC needs to consistently apply such an approach to implementation of the entire regulation, beginning with the selection Chemicals of Concern and Priority Products, to the identification of an AA Threshold, throughout the AA process and in the determination of appropriate and proportionate regulatory responses. The proposed regulation raises significant concerns that the Department does not intend to consistently apply an objective, science-based process, but instead structure and administer a program that responds to the latest sensationalist media story or activist agenda. The concerns start with the use of the narrative standard, which is ultimately subjective and facilitates a political, not scientific, basis for prioritization. Inadequate definitions for "reliable information" and "reliable information demonstrating the occurrence of exposure" provide additional reason for concern since neither definition requires a means to assess the quality of information. Concerns are further exacerbated with an absence of emphasis on a weight-of-evidence evaluation of information. Instead, dependence rests upon the "most protective" study independent of its actual quality and reliability. Indication that decisions should be driven by the "greater amount of information" rather than conclusions from the most relevant and highest quality studies further alarm the reader that an objective, science-based process is absent from the proposed regulation.

We strongly assert that DTSC's evaluation of information to make decisions and substantiate conclusions about "the ability of the chemical to contribute to or cause adverse public health and/or environmental impacts" need to be guided by the following principles:

- The decision-making process must meet benchmarks of objectivity, transparency, and scientific accuracy needed for stakeholders to have sufficient confidence in the Department’s health and environmental regulatory decision-making.
- All evaluations must rely on the best available scientific information regarding possible hazards and risks of substances, and employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure.
- DTSC must establish upfront, transparent criteria and then consistently apply the criteria throughout the evaluation process to identify studies and to evaluate their quality, relevance, and reliability.
- DTSC must base all evaluations on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.
- DTSC must objectively characterize and present hazards and risks in a manner understandable to stakeholders and risk managers and provide a full picture of what is known and what has been inferred.
- Assessments must provide full disclosure of key information. When DTSC uses assumptions (or policy preferences) in lieu of scientific data, DTSC must disclose the assumptions (and policy preferences) along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.
- Processes need to be in place to ensure that public comments and peer review findings and recommendations are fully addressed.

DTSC should incorporate these principles into Article 1 of the regulation to provide the overall theme and foundation for science-based implementation.

### **Specific Issues**

#### **Article 1 - §69501 General**

**§69501.1 – Definitions.** Definitions for “**adverse impacts**”, “**reliable information**” and “**reliable information demonstrating the occurrence of exposures**” remain scientifically inadequate. They focus on the existence of a hazard or exposure only. No thresholds are included to account for potency and likelihood of harm in making decisions and implementing the regulation.

**(19) Chemical** – A chemical ingredient is one that is intentionally added to serve a function in the final product and should be the focus of this regulation for the reasons discussed throughout these comments. The following revision is suggested:

“Chemical” means [19(A)(1)...] ~~or~~ **and intentionally added above the Alternative Analysis threshold to serve an intended function** in a consumer product.

The “molecular identity” definition appears in 19(B) to clarify use of this term in the description of “chemical” in 19(A)(1). The definition of “molecular identity” has been expanded to include consideration of physical properties of ingredient. This seems appropriate since these properties are routinely considered in the safety assessment of products and their ingredients. The relevance of these physical properties will depend on the application and use of the ingredient and not all will be relevant for a determination of safety. This decision can only be made as part of a risk assessment process by an assessor knowledgeable about how the ingredient is used. We applaud the DTSC for recognizing this need for expert judgment in the proposed regulation and encourage you to maintain your commitment to this in the final application of this regulation.

**(22) Consumer Product** – The consumer product definition in the proposed regulation revokes the bulk chemical exemption that appeared in the October 2011 informal draft as §69501(b)(2). This change is inconsistent with the focus of the Safer Consumer Product Alternatives Regulation to find functionally acceptable and technologically and commercially feasible alternatives for Chemical(s) of Concern in Priority Products widely used in consumer homes throughout the state. The California Division of Occupational Safety and Health (Cal/OSHA) protects workers from safety hazards and unreasonable exposures in the occupational environment within the state. Similarly, the Occupational Safety and Health Administration (OSHA) enforces workplace safety and health at the federal level. The Department of Transportation (DOT) and Department of Homeland Security (DHS) regulate the movement and transport of bulk chemicals, so a regulatory infrastructure already exists at the federal and state level to protect (and manage any improvements) in the health and safety of California’s workforce. The inclusion of bulk chemicals within the scope of the proposed regulation presents a case of regulatory duplication.

**(31) Functionally acceptable** - The regulation proposes a change from the earlier draft definition, which stated that the alternative “substantially equals or exceeds the performance and functionality of the original product.” The proposed definition appropriately recognizes the importance of consumer acceptance of an alternative in the overall evaluation of “acceptable” (i.e., “the product performs the functions of the original product sufficiently well that a consumer can reasonably be anticipated to accept the product in the marketplace”). Recognition is needed that consumer acceptance is not directly and quickly measurable and may add many months to the AA timeline to enable sufficient consumer testing to draw a conclusion.

**(34) Homogeneous Material** – DTSC has eliminated the earlier recognition of “assembled product” and replaced with the new term, “homogeneous material,” in this proposal. A homogenous material could potentially become the focus of an AA by being defined as a “product” which means, among other things

"A component, or a homogeneous material within a component, that is identified, under section 69503.4(a)(2)(B), as the minimum required focus of an AA."

While six substances are restricted at the homogenous material level in electronic products in European Union's Restriction of Hazardous Substances (RoHS) Directive, this concept is not appropriate for the scope of chemicals and products that will be covered in the California regulation. There would be great difficulty and uncertainty in defining it and in the case of polymers there would be an infinite number of variations. Beyond the impracticality, it's not clear why this is needed – "component" should satisfy all needs for the focus of an AA. For the following reasons, we recommend removal of this term and that the regulation focus on "component" in addressing assembled article types of products.

- Very difficult to enforce compared to a focus on the component level. A company cannot easily test to this definition, creating ambiguity for both the agency and regulated community
- Currently this is a specific regulatory term for a single sector (electronic industry) and applies only to a small number of regulated substances – not broadly applicable nor scalable to other consumer product sectors
- Information on assembled products is being collected in supply chains at the level of component / article for substances of very high concern under REACH. The homogeneous materials concept brings into question whether these data would be applicable for California, resulting in longer implementation timelines and significant additional administrative burden for agency/industry with minimal environmental benefit.

**(38) Legal requirements** - Regulations in other states or countries are not acknowledged in the proposed regulation. For instance, many products are made for the North American or even global market. The following revisions are suggested:

"Legal requirements" means specifications and/or performance standards that a chemical, ~~or~~ a product, ~~or~~ product packaging **or labeling** is required to meet by federal, California **or other state or international** law.

**(52) Reliable Information** – While there are some helpful improvements to this definition, DTSC has yet to address or resolve the fundamental problem. The revised definition identifies a wide variety of sources of scientific information and makes a *de facto* determination that they are "reliable." All of the sources mentioned are appropriate for consideration in making decisions. Some include deliberative scientific processes that actually review the information in studies and judge weight-of-evidence and other factors (e.g., National Academies and reports from government agencies). In such cases, they may be considered reliable. However, defining "reliable" information from sources not widely recognized in the scientific community as "authoritative bodies" unnecessarily introduces question, and potential controversy, into a program that is intended to be science-based. For example, the reference in (A) is problematic: "Published in a scientifically

peer reviewed report or other literature.” “Other literature” is open-ended and could include all manner of unreliable information.

What would DTSC do in a case where there are four peer-reviewed studies that provide entirely different results, or four studies from a variety of the listed sources that come to different conclusions? By the Department’s current definition they are all “reliable information.”

The need for a mechanism to judge studies for relevance and reliability is widely recognized by federal agencies with health and safety responsibility and in international forums. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology has been used for determining data quality and reliability on tens of thousands of studies for over 2,000 chemicals in U.S. and OECD High Production Volume (HPV) programs. The hundreds of thousands of studies on over 5,000 chemicals that industry has submitted under REACH were rated according to this approach. The methodology is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies<sup>4</sup>.

We reiterate the recommendation that industry has presented to DTSC in earlier, informal draft versions of the proposed rule to provide separate definitions for “Information Sources” to include the diverse sources listed in (52) and (53) and then to determine reliability by subjecting those studies to this definition for “Reliable Information” based on the OECD Manual:

*“Reliable information” is from studies or data generated according to valid accepted testing protocols in which the test parameters documented are based on specific testing guidelines or in which all parameters described are comparable to a guideline method. Where such studies or data are not available, the results from accepted models and quantitative structure activity relationship (“QSAR”) approaches validated in keeping with OECD principles of validation for regulatory purposes may be considered. The methodology used by the Organization for Economic Cooperation and Development (OECD) in Chapter 3 of the Manual for Investigation of HPV Chemicals (OECD Secretariat, July 2007) shall be used for the determination of reliable studies. [http://www.oecd.org/document/7/0,2340,en\\_2649\\_34379\\_1947463\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html)*

**(54) Responsible entity** – The only relevant responsible party that should be identified is the entity identified on the product container. The Department should use the Federal Trade Commission’s (FTC) Fair Packaging & Labeling Act (FPLA) recognition of a responsible entity in lieu of the current definition in the proposed regulation, providing for uniformity of laws and the use of an existing system also used by other regulatory agencies (California Air Resources Board-ARB, CPSC, etc.). All consumer commodities that are legally distributed in U.S. commerce must comply with the Federal Trade Commission labeling requirements, so identification of the responsible entity is simple. As such, subsections (B) and (C) should be eliminated.

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<sup>4</sup> [http://www.oecd.org/document/7/0,2340,en\\_2649\\_34379\\_1947463\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/7/0,2340,en_2649_34379_1947463_1_1_1_1,00.html).

**(56) Safer alternative** – Recommend a change in the definition: “Safer alternative” means a **functionally acceptable** alternative that, in comparison with the existing Priority Product, ~~reduces, avoids, or eliminates the use of, and/or potential exposures to, one or more Chemical(s) of Concern, so as is determined by the~~ **Alternatives Analysis** to reduce adverse public health and environmental impacts.

**(58) Sensitive subpopulations** - The definition of “sensitive subpopulation” refers to “individuals with a history of illness” and “workers.” The reference to “a history of illness” is exceedingly broad and somewhat ambiguous as to what constitutes “illness.” We recommend deleting this reference to individuals with a history of illness (or modifying the term to conform to DTSC’s intent to cover only those “serious” or “chronic” illnesses affecting a meaningful portion of the population). DTSC should also delete all references to workers (whose health is regulated by Cal/OSHA) before finalizing the regulation.

**Adverse Impacts** – Adverse impacts and chemical properties are defined for air quality, ecological, public health, soil quality, water quality, and waste/end-of-life related to hazard traits. Many traits are traditional endpoints addressed in state, federal and international chemical programs. However, there are several critical concerns in these definitions.

**Reliance on Emerging Science** –The first is that some factors recognize scientific frontier issues—for instance epigenetic toxicity—that are not settled science and lack widely accepted evaluation methodologies. These factors appear in the proposed regulation because they are included in OEHHA’s hazard traits. We fully support ACI’s written comments on the OEHHA Green Chemistry Hazard Traits regulations (Chapter 54), which are currently available on the OEHHA website.<sup>5,6</sup> As discussed in ACI’s comments, the OEHHA hazard trait regulation includes many elements that are unauthorized by the statute, unnecessary to effectuate the purpose of the statute, inconsistent and duplicative of other California statutes, and do not comport with current scientific consensus. As such, DTSC’s proposed regulation should not reference Chapter 54.

**Thresholds** – An overriding concern with the adverse impact and chemical property definitions is that there are no threshold levels to provide a context for what is of concern. The absence of thresholds in the proposed regulation suggests that every substance could be considered a Chemical of Concern or be included for the purposes of AA Threshold determination, Alternative Analysis and regulatory response because it has some impact, regardless of potency. Thresholds are a part of chemical control systems worldwide as a means to help identify priorities. The definitions should include thresholds and clearly convey the potential for adverse impacts in the context of thresholds.

**Bioaccumulation** – Industry stakeholders have previously noted that the proposed definition for bioaccumulation is inconsistent with nationally and internationally accepted definitions, which specifically include thresholds. Peer reviewers have also commented on this issue. In this iteration,

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<sup>5</sup> <http://www.oehha.ca.gov/multimedia/green/pdf/Feb2011/ACI022811.pdf>

<sup>6</sup> <http://www.oehha.ca.gov/multimedia/green/pdf/Sep2011/ACI.pdf>

there is further confusion by reference to both the previous DTSC definition AND a reference to OEHHA's hazard traits. It's not clear why such an important chemical property, with a long history of federal and international standard setting and chemical control actions, should be defined uniquely in California. We join our industry partners in reiterating the recommendation that DTSC change the bioaccumulation definition consistent with the Society of Environmental Toxicology and Chemistry's (SETAC) Pellston workshop on Persistent Organic Pollutants (POPs) and Persistent, Bioaccumulative and Toxic chemicals (PBTs) that explored the current state of bioaccumulation science.<sup>7,8</sup>

**§69501.2 – Duty to Comply and Consequences of Non-Compliance.** In Section 69501.2(a), the requirements for compliance should be limited to the manufacturer of the product or responsible entity as identified on the product label, per the requirements of FPLA. The manufacturer has the knowledge of the formulary science that produced the Priority Product and is the most knowledgeable entity in the supply chain to manage the AA requirements, including the potential selection of a functionally acceptable alternative that is compatible with the product formulation. As such, references to the importer or retailer should be eliminated.

**§69501.4 – Chemical and Product Information.** Under subsection (a)(4), the Department would give itself unlimited authority to require a manufacturer or importer to generate and obtain information with no accountability. There should be boundaries regarding the kind of information that the Department may seek, and due process for those to whom the Department is making the request.

**§ 69501.5 – Availability of Information on the Department's Website.** The Department should use official state regulatory dissemination methods (e.g., California Regulatory Notice Register) as the primary means of communicating its policies and decisions regarding the Safer Consumer Product Alternatives Regulation.

## **Article 2 - §69502 Chemicals of Concern Identification Process**

The proposed regulation starts with a consolidated list of chemicals from 22 source lists at the effective date of the Regulation, resulting from the merging of all the items on the lists. These lists contain well over 4,000 distinct chemicals. Though DTSC has indicated that the published list will contain 1,200 chemicals, the Department has not indicated how the reduction will take place other than to take out the approximately 450 pesticides and pharmaceuticals that are exempted from the regulation.<sup>9</sup> There are several major concerns with this approach, as follows:

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<sup>7</sup> Gobas, F.A.P.C., W. de Wolf, L.P. Burkhard, E. Verbruggen and K. Plotzke. 2009. Revisiting bioaccumulation criteria for POPs and PBT assessment. *Integrated Environmental Assessment and Management*, 5(4):624-637.

<sup>8</sup> <http://www.setac.org/sites/default/files/ExecutiveSummary.pdf>

<sup>9</sup> This regulation, like every other chemical regulation, must specify unique Chemical Abstract Services numbers (CAS RN) and cannot utilize generic chemical categories. For instance, the perfluoro chemical category contains many hundreds of different unique CAS RN chemicals. Responsive compliance and the enforceability of the regulations requires the clarity of a unique CAS RN associated with Chemical of Concern lists and carried through each subsequent element of the regulation.

- The statute requires that DTSC establish a process to prioritize Chemicals of Concern. The proposed regulation does not articulate a prioritization process whatsoever, and therefore, does not deliver the statutory mandate.
- While listing 4,000 or 1,200 chemicals may give the appearance of providing expansive public protection, the action creates a meaningless and untargeted concoction. Nearly 50% of the over 4,000 substances are not even listed on the TSCA Inventory, making them illegal in US commerce<sup>10</sup>. More than 80% were not reported as manufactured or imported into the US in EPA's most recent Chemical Data Reporting (CDR) Rule update; and 90% are not used in consumer products.
- The establishment of a non-credible list of 4,000 or even 1,200 substances will become irrelevant and do little to motivate broad-based, proactive action by manufacturers. The overwhelming number of chemicals on this list likely drive manufacturers to focus resources only on those identified as Chemicals of Concern in selected Priority Products.
- It is much more appropriate to refer to this larger list as "Chemicals of Interest" (or similar), and for DTSC to establish a narrowed list of "Chemicals of Concern."

Actual prioritization of Chemicals of Concern gives credibility to the process and will make the regulation consistent with statutory mandate. The Department indicates that they will identify approximately 185 Chemicals of Concern for the initial focus of the program through 2016 representing the most severe hazard traits. We strongly support the wisdom of starting with a manageable number of chemicals which the Department will identify based on chemical hazard information together with indicators of exposure. This is a critically important step; DTSC's identification of a focused, core group of substances will allow the Department to learn while making progress in the initial years of the program, and concurrently send an important signal to the marketplace.

Moving beyond the commencement of the program, there should be a periodic (and transparent) process by which the Department identifies a narrowed list of chemicals on the basis of hazard and indicators of exposure. We recommend the following approach to prioritize Chemicals of Concern to a narrowed and focused list:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes. Provide opportunity for stakeholder input and comment (specific recommendations below);
- Merge those lists to generate a set of "Chemicals of Interest;"

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<sup>10</sup> Not all chemicals require inclusion on the TSCA Inventory, as specified in the exclusions to TSCA (TSCA § 3(2)(B)) and exemptions from Pre-Manufacturer Notification requirements (TSCA § 5(h)(4)).

- Conduct an actual prioritization/screening to identify real Chemicals of Concern. This would encompass several steps:
  1. Remove from the merged list pesticides, pharmaceuticals, and other substances that are not chemical substances to which the regulation applies.
  2. Narrow the result from above to only those chemicals permitted in commerce in the U.S. using the TSCA Inventory of Non-Confidential Chemical Substances, publicly available on U.S. EPA's website<sup>11</sup>, and FDA and other exposure information such as Centers of Disease Control and Prevention (CDC) biomonitoring data<sup>12</sup>;
  3. Further narrow the result to chemicals that are in U.S. commerce in significant volumes using EPA and FDA information. The U.S. EPA's most recent publicly available data from the CDR Rule will identify all chemicals manufactured or imported into the United States at volumes >25,000 lbs. The CDR data reflect the most current, comprehensive snapshot of chemicals actively used in US commerce, and importantly, indicate the consumer product categories in which these chemicals are used. DTSC can also use the CDR data to identify chemicals for which respondents indicated use in products intended for children age 14 and younger.
  4. Publish the proposed Chemical of Concern list for public comment.
  5. Finalize the list.

As noted above, a variety of source lists are appropriate and will be useful as a starting point in a true prioritization process. We recognize and commend DTSC efforts to modify the previous draft of source lists to better represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment. However, there are several remaining concerns, as follows:

- (1)(C) is the European Union's (EU) endocrine disruptor list. The European Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE), the EU's most prestigious scientific body for toxicity testing, discredited this work because initial compilation of the list did not include a deliberative scientific process with opportunity for stakeholder input. Additionally, there is no conclusion on adverse impact, and therefore the listed chemicals may or may not be endocrine disrupting. Endocrine activity is not a distinct toxicological end point per se, but rather a measure of a chemical's ability to interact with components of the endocrine system. We recommend DTSC drop the EU list, with the assurance that chemicals identified as reproductive or developmental toxicants will capture chemicals that disrupt the endocrine system.

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<sup>11</sup> <http://www.epa.gov/oppt/existingchemicals/pubs/tscainventory/howto.html>

<sup>12</sup> <http://www.cdc.gov/biomonitoring/>

- (1)(H) is Canada’s prioritization list of potential Persistent, Bioaccumulative and Inherently Toxic (PBT) compounds, completed in 2007 and mostly based on modeling results. Since that time Environment Canada has conducted hundreds of assessments in its Chemical Management Program leading to determinations in a number of cases that a chemical is not PBT. The Department should adopt the Chemical of Interest and Chemical of Concern lists utilizing the most up-to-date information from Environment Canada.
- (1)(I) is the International Agency for Research on Cancer’s (IARC) Carcinogen list. The IARC Group 2B list is comprised of substances for which there is limited human evidence and insufficient animal evidence of carcinogenicity.<sup>13</sup> DTSC should not include IARC Group 2B as a Chemical of Concern source list in the final rule.
- (1)(L) is the Office of Health Assessment and Translation reproductive and developmental toxicants. While we agree that this is an authoritative source, DTSC should only reference those chemicals identified by this Office as “Serious Concern” and “Concern.”
- (1)(N) The Washington State PBT list did not use criteria consistent with the US EPA PBT list and should be removed.
- (2)(F) is the California Biomonitoring program that remains in early stages with little completed (or validated) testing. DTSC should not consider listed chemicals in this program that are beyond the scope of the CDC Biomonitoring program and have yet to be studied as those having “exposure information.”
- (2)(H) The OSPAR list is not authoritative. Initial compilation of this list did not include a deliberative scientific process or opportunity for stakeholder input.

**§69502.2(b) - Additions to the Chemicals of Concern List.** The narrative standard for identifying additions to the Chemicals of Concern list is not sufficiently transparent. The Department needs to provide additional clarity to this process so that it is objective and repeatable if conducted by different sources. There is no indication what sorts of thresholds for the factors would be used in selecting additional Chemicals of Concern.

### Article 3 - §69503 Product Prioritization

As discussed in every P&G submission to DTSC throughout the development of the regulatory framework for the California Green Chemistry Initiative, we continue to fully support and strongly recommend a science-based prioritization process for Priority Products. Such a process would require the Department to evaluate hazard and exposure in prioritization actions to focus on those situations with the greatest potential for

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<sup>13</sup> World Health Organization International Agency for Research on Cancer Monographs on the Evaluation of Carcinogenic Risks to Humans, Preamble, p. 23.

significant exposures to the Chemical of Concern used in product in a quantity that can result in adverse public health or environmental impacts.

We recognize that the Department has made a number of improvements in this section over previous drafts and we support the continued inclusion of the following elements in the final rule:

- Consideration of both hazard and exposure to set priorities
- The focus on real health and environmental concerns over theoretical exposure
- The inclusion of “frequency,” “extent,” “level” and “duration of exposure” in §69503.2(a)(1)(B)(4)(c) which describes the approach for quantifying exposure in use and end-of-life scenarios
- The tightening of Key Prioritization Factors and requirement that Chemical of Concern/Priority Product pairs must meet both criteria of (1) a significant ability to contribute to or cause adverse public health and environmental impacts AND (2) a significant ability for the public... to be exposed to the Chemical of Concern in product...
- The concept of a Priority Product Workplan outlining the Department’s direction for 3 year periods.

We encourage DTSC to give greater attention to quantitative evidence of actual exposure (when available) in the prioritization process rather than rely solely upon indicators of exposure. Presence of a chemical in a consumer product is not the same as exposure, but simply presents a scenario where consumer exposure *may* occur. A number of additional factors contribute to actual exposure, including concentration of a Chemical of Concern in a Priority Product, accessibility to the Chemical of Concern during product use, use patterns of the product, frequency and duration of use, and method and site of application. Presence of a Chemical of Concern in a Priority Product is only one piece of the exposure puzzle. Quantitative information demonstrating exposures at levels of concern must be a driving factor in prioritization decisions.

**§69503.2(a)(1)(B)(4)(b)(iii)** - Worker exposure is within the exclusive jurisdictional purview of Cal/OSHA, which occupies the field in ensuring and addressing exposures in the workplace. This subparagraph should be deleted in its entirety, as well as any other references in the regulation to “workers,” “worker exposure” or “workplace.”

**§69503.2(a)(2)** - The need for emphasis on quantitative information demonstrating exposure in the prioritization process provides reason to question the practicality of the Key Prioritization Factor that states “the Chemical(s) of Concern in the product have a significant ability *to contribute to* or cause adverse public health and environmental impacts.” The “contribute to” language suggests that DTSC consider aggregate and/or cumulative exposure potential of a Chemical of Concern to cause adverse impacts without providing any indication as to how DTSC will obtain or evaluate this information. The regulation needs to specify the

methodology and data with which DTSC will evaluate a Chemical of Concern as “contributing to” adverse impacts to remain as a Key Prioritization Factor in the final rule. The assessment of aggregate and cumulative exposures is very complex and currently lacks the guidance of available and validated scientific methodologies. For this reason, we urge DTSC to remove the “contribute to” language from the Key Prioritization Factor since aggregate and cumulative exposure science is not yet well established.

The proposed regulation has abandoned any focus on intentionally-added ingredients, which are those chemicals that manufacturers purposefully formulate in a product to perform a function. DTSC should not designate consumer products that contain Chemicals of Concern as Priority Products if the presence is due to typical low-level impurities in raw materials that are not a concern for safety and are not economically feasible to remove. A focus on chasing unintentional trace levels of chemicals will significantly diminish or eliminate the meaningful improvements in public health and environmental protection expected of the program. As in our previous comments to DTSC, P&G strongly recommends that DTSC consider only chemicals that are intentionally-added above the AA threshold level when making product prioritization decisions.

In selecting Priority Products, the Department should use a standardized product nomenclature system. We note that the ISOR makes reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing Section 69503.3(f). We agree that the GS1 GPC is the appropriate source for describing products and recommend that DTSC identify Priority Products at the Brick Level, consistent with the approach already implemented by the States of Maine and Washington in their children’s product regulations. DTSC should describe Priority Product categories at the Class Level for the purposes of the Department’s Priority Product Work Plan.

**§69503.5 – Alternative Analysis Threshold Exemption.** DTSC should eliminate the Alternative Analysis Threshold Exemption Notification process in favor of a risk-based, self-assessment process. OEHHA uses a risk-based, self-assessment process under the Proposition 65 (Prop 65) Safe Harbor provisions for companies to determine whether they have to provide a warning statement on the product label. This aspect of Prop 65 has been very successful and could serve as a model for the application of the AA Threshold Exemption provisions of the Safer Consumer Product Alternatives Regulation to minimize administrative burden.

**§69503.6 – Alternative Analysis Threshold Exemption Notification.** According to the requirements of this section, a manufacturer will need to substantiate an assertion in the AA Threshold Exemption Notification that a Chemical of Concern is *not* present in a Priority Product with “laboratory analytical testing protocols and results used to detect and measure the concentration of the Chemical of Concern in the product.” To complete this testing, a manufacturer must have the capability to develop and validate test methods that will be reliable for a particular formulation. Even when a validated test method is already available, the process to substantiate an AA Threshold Exemption Notification will be lengthy and cumbersome. Each notification will require testing with lab QA/QC protocols to produce data on all product variations, summarization of all data, management signature and approval, followed by submission to DTSC. This is particularly distracting in the current landscape of scarce, stretched resources and competitive business challenges that demand full attention on delivering the next big innovation. These R&D resources will need to be pulled away from

constructive work to demonstrate a negative – that a Chemical of Concern, with which we do not intentionally formulate, is not present in our product. Reliance on detailed specifications already in place with raw material suppliers to ensure our ingredients meet quality criteria should be sufficient information to use in a self-assessment process similar to the OEHHA Safe Harbor process discussed above. A manufacturer could provide DTSC with the information used to substantiate the self-assessment upon request.

P&G has consistently advocated for the inclusion in the proposed regulation of a 0.1% *de minimis* threshold for intentionally-added Chemicals of Concern in Priority Products. The Practical Quantification Limit (PQL) approach that appears in this proposal requires regulatory compliance for Chemicals of Concern at detection levels in a Priority Product. With continuously improving analytical capability and ever-lower detection limits, analytical labs can identify small and insignificant levels of trace chemical presence in consumer products. The exposure to such trace chemicals is infinitesimal at best; the control of which is meaningless in protecting public health. Threshold provisions are standard in a variety of international chemical and product safety laws. Europe's REACH chemical law applies a 0.1% *de minimis* level as a default, even to the so-called Substances of Very High Concern. The European Cosmetic Directive also includes a 0.1% *de minimis* level for over 1,300 carcinogens and reproductive toxicants. Worker and transportation regulations in Europe and North America and the U.S. chemical control statute, TSCA, also contain provisions that recognize a 0.1% *de minimis* threshold. We strongly encourage California to remain consistent with other national and international laws that recognize the logic that the low, but measurable, levels in consumer products do not create significant exposures that present a likelihood of harm.

The importance of a default *de minimis* provides certainty and predictability to the regulated community in terms of their compliance responsibilities. Without a default threshold, manufacturers are left confused as to whether they or their brands are within scope of the regulatory compliance obligations, forcing manufacturers to conduct unnecessary and expensive testing to detect trace chemical presence that has no bearing on objective safety but may tip them into compliance scope. That said, we do support the concept that DTSC should have the flexibility to adjust the default *de minimis* based on sound science and reliable information. Experience in the European Classification system (EC No. 1272/2008) is that 85% of the over 4,000 chemicals with classified hazards are bound by a 0.1% threshold; the EU has determined a different threshold level – sometimes lower, sometimes higher - for the remaining 15% of chemicals.

#### **Article 4 - §69504 Petition Process for Identification and Prioritization of Chemicals and Products**

We commend DTSC for including a petition process that allows the *removal* of Chemicals of Concern and Priority Products from the appropriate lists. However, we do not understand why DTSC has not extended this same policy to entire lists of chemicals. A petitioner may seek addition of an entire list of chemicals, but no allowance exists for a petitioner to request the reverse. DTSC should allow petitions to *remove* entire lists of chemicals as well.

We strongly assert that all petitions which DTSC deems complete and acceptable for merits review require public notice and comment prior to the Department's final decision whether to grant or deny the petition.

## Article 5 - §69505 Alternative Analysis

**Summary Comments.** The alternatives analysis process is essential for developing safe and innovative consumer products. The fundamentals of the process are routinely executed as part of industry's ongoing research and development (R&D) and product design processes. As we have shared repeatedly with DTSC, P&G designs safety into our product development process right from the start. We incorporate green chemistry thinking and screen potential new ingredients for severe hazard “show stoppers” as a preliminary step to narrow the field of potential candidate ingredients to those that show promise for further assessment. Our research then proceeds with evaluation of the technical acceptability of candidate ingredients; with the gathering of more information on the hazards of the chemicals, the planned uses and anticipated exposure pathways; and the completion of a refined risk assessment to make final decisions about the ingredients we will use in our trusted brands. This risk assessment process is based upon an informed evaluation of both the hazard of the candidate ingredient and the anticipated exposure consumers will experience upon use of a product in which the ingredient is formulated. We assimilate robust information into the safety assessment that we have gathered on the hazards of the chemical, toxicity study data, intended use and application of the finished product, and world-leading understanding of observed consumer habits, practices and preferences to fully understand and anticipate the risk profile of each new ingredient. Only after we have assured ourselves of the safety of a new ingredient and the finished product in which it is formulated, do we move forward with marketing and scale operations to send the product to market.

A rational alternatives analysis process in a regulatory framework that parallels the key evaluation and decision approaches in the R&D and product design processes is essential from a business perspective. Such a framework must provide the opportunity for a manufacturer to fully demonstrate the safety of a Priority Product as an initial step before proceeding with an analysis of acceptable alternatives. It is this piece of the regulatory framework to which we see too little attention applied in the proposed regulation. Rather, the proposed regulation is threaded throughout with an emphasis on the search for alternatives to Chemicals of Concern and to “maximize the use of alternatives of least concern.” “Alternative” by virtue of the DTSC definition in Article 1, means a change selected from possible options. P&G contends that “no change” is an equally probable conclusion for a Priority Product after a risk-based evaluation of hazard, use and exposure. DTSC’s failure to fully appreciate and equally consider “no change” as a completely acceptable outcome will deny California consumers the continued freedom to choose products that they have come to know and trust to meet performance expectations, and the real possibility that California will miss opportunities to experience meaningful environmental benefits delivered by sustainable innovations.

DTSC must not create a regulatory AA process in which the Department compares manufacturers’ AA reports and chooses a particular alternative to mandate across industry. Every product has unique formulary chemistry and attributes, and a decision that a single alternative is the best solution for all products within a single category will be the wrong decision. Rather, DTSC needs to evaluate AAs based upon their own merits and compliance with the statutory requirements. A manufacturer has met their statutory obligation when they

complete and submit an adequate AA within the mandated timeline. The choice of the most technologically and commercially feasible alternative needs to remain solely with the manufacturer, who is the most informed entity capable of judging such feasibility within their unique business model.

**Positive Elements to Retain in the Final Rule.** We are pleased to see elements within the Alternatives Analysis section of the proposed regulation that are consistent with counsel we have provided DTSC over the years based on our experience with life cycle thinking and alternatives analysis. Positive elements that appear in this section and which DTSC should retain in the final rule include the following:

- Recognition that the design and conduct of an AA can pull from a number of available tools and methodologies. We commend the Department for allowing flexibility in a manufacturer's approach to the structure and completion of an AA for a Priority Product.
- Opportunity for a manufacturer to submit an abridged AA report when a "functionally acceptable" alternative is not available and further evaluation is not useful. We recommend DTSC allow a manufacturer to use the abridged AA path to demonstrate the Priority Product's safety and overall acceptable risk profile. This will allow a manufacturer to avoid the cost and significant resource allocation of the AA process that will deliver a reformulated Priority Product comparable in safety profile to the original formulation, but with trade-offs that could equate to inferior quality.
- The allowance for individual chemical manufacturers and/or formulators to complete an AA for a Priority Product or to join with industry partners in a consortium that represents an industry segment or an entire industry. Such an allowance will minimize resource expenditure, streamline administrative burden and allow manufacturers to share and build upon subject matter expertise and best practices.
- Recognition that multiple factors influence the decision-making process and ultimate selection of a technologically and commercially feasible alternative. Such a holistic analysis is needed to minimize potential trade-offs (both known and unintended) and avoid missed opportunities. The safety, compatibility, effectiveness, life cycle contributions, sufficient commercial availability, cost, compatibility with manufacturing lines, and likely **consumer acceptance** are all very relevant and appropriate considerations in an alternatives analysis. We thank the Department for listening and responding to our consumer insights and experiences that prove consumers generally will not accept trade-offs in product performance or an increase in price of their trusted brands after reformulation with an alternative. Without consumer demand, there will be no meaningful improvement in public health or environmental benefit because consumers will not replace existing products or practices with the new alternative. Instead, we have found that, when trade-offs occur, frustrated consumers will often resort to approaches such as "homebrew" concoctions or other practices that increase the risk of harm or injury. P&G commends the Department for understanding that the AA process must

include steps to identify and weigh all of these multiple factors to create a workable, practical, and meaningful Green Chemistry program in California.

- Acknowledgement that manufacturers have expert, in-house practitioners with a wealth of experience in AA and life cycle thinking who are fully capable of serving as Lead Assessors for the AA on their company's Priority Product. DTSC rightfully acknowledges that experienced practitioners understand available AA methodologies and tools from which they can choose to apply in a focused AA. The provisions allow these Lead Assessors to focus an AA on the critical parameters within a multi-factorial evaluation matrix that truly drive an alternative decision for a product. The familiarity with a manufacturer's Priority Product formulation allows an in-house practitioner to streamline resource expenditure and make the best selection of alternatives to minimize unacceptable trade-offs and/or risk for California consumers and the environment.
- Allowance for the Priority Product manufacturer to make the ultimate selection of an acceptable alternative based on findings during the AA process and best fit within their unique business model. DTSC will review AA reports for completeness and statutory compliance and implement a regulatory response, for which the Priority Product manufacturer can make recommendations as part of the final AA report. The way in which DTSC has constructed the proposed AA provisions demonstrates to us their appreciation for a manufacturer's informed decision-making process to achieve effective results.
- Inclusion of an Implementation Plan in the final AA report that provides a manufacturer with some flexibility to tailor the time needed to implement an alternative (including the steps necessary to ensure compliance with other federal and state laws).

**Opportunities for Improvement in the Final Rule.** While we acknowledge the many thoughtful improvements DTSC has incorporated into the AA provisions in response to industry outreach and dialogue, we continue to believe the proposed rule contains certain challenges to a practical and effective AA process for California's regulatory framework that require attention and modification for the final rule. From our decades of experience with alternatives analysis, we offer the following recommendations to ensure the AA construct for California establishes a workable process with realistic expectations and maximum opportunity to achieve Director Raphael's vision of meaningful (and measurable) improvements in public health and environmental protection:

1. **Codify the expectation that a "functionally acceptable" alternative encompasses consumer acceptability, compliance with legal requirements and delivers a finished product that meets or exceeds performance of the original Priority Product.** "Performs sufficiently well" (see §69501.1(a)(31)(B)) is not an acceptable criterion for a functionally acceptable alternative because the weak language suggests a lower or mediocre level of product performance and some level of trade-offs. As discussed earlier, consumers are not willing to accept trade-offs in performance and price; therefore, a "functionally

acceptable” alternative can only be one that does not change or improves the consumer’s experience. Otherwise, market economics will de-select the alternative and the program will fail to deliver any meaningful improvement in public health or environmental protection, following a significant expenditure of resources (both of the manufacturer and DTSC).

- 2. Incorporate reasonable timeframes for preparing AA reports.** The current allowances in the propose regulation (i.e., six and 12 months for preliminary and final AA reports, or 60 days and 18 months for AA workplan and final reports) are not practical. These tight timelines will prove unworkable should there be a need to do further experimental research to evaluate a particular alternative or development of a consortium or public-private partnership approach to accomplish the AA work.

A manufacturer will need more than 18 months to identify one or more functionally acceptable and commercially viable alternatives. The reality is that industry has already completed the “easy” alternative substitutions. A new alternative analysis will require several steps that illustrate the complex, lengthy process a manufacture undertakes to identify and implement a functionally acceptable and commercially viable alternative. The process begins with laboratory research by formulary scientists to identify possible alternatives that will function as intended and remain stable and compatible within the product formula matrix. The scientists work closely with toxicologists who assess and compare the safety profiles of the original product and potential alternative formulations. Once the manufacturer identifies a viable alternative (a discovery and development process that can require 3-5 years or more), the manufacturer will conduct market research to gauge consumer acceptance and identify any unforeseen trade-offs before selecting the most viable alternative. Consumer research is an iterative process that begins with laboratory-made samples but progressively advances to realistic prototypes produced from manufacturing pilot runs, an extensive operation which requires scale-up (and possible re-tooling) of manufacturing lines. Importantly, any step along this lengthy process can (and often does) reveal failed alternatives that can send the process back to the beginning.

Our experience with the product development process indicates that a “simple” chemical substitution in a formulated product requires a minimum of two months to coordinate scientists and engineers in the lab; one year of research to find a material that meets safety requirements, economic constraints, sufficient supply quantities, etc.; three months of process lab testing; six months for testing at the manufacturing plant (which requires scheduling of an experimental run since plants typically run at capacity); three months of consumer testing (not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). At least 26 months are necessary to complete the R&D process from the time one or a few materials are identified for further assessment. This timing holds true **only if** the identified alternative is acceptable for commerce in the United States. If the alternative is a new chemistry, the product manufacturer will likely have to submit a TSCA Pre-Manufacture Notification (PMN) to EPA, or enlist the chemical supplier to submit the PMN. With this additional federal compliance requirement, the needed timing to complete an AA extends to at least three years. (EPA may request additional data generation during review of a PMN that could extend the

standard 90-day EPA review period. For this reason, it is important that DTSC provide an option for a manufacturer to request an extension of the allowable AA timing.)

In most situations, chemical substitutions with acceptable alternatives will be much more complex than the aforementioned “simple” substitution. Substitution of a single Chemical of Concern may require multiple substitute alternatives if the Chemical of Concern performs different functions within the product formula matrix. A good example of this scenario is the replacement of phosphate in auto dishwashing (ADW) products. The replacement of phosphate required four to five different materials (depending on the ADW formulation) and initially took three years to complete. P&G’s experience with phosphate replacement in Cascade ADW required submission of a TSCA PMN in the United States and two New Substance Notifications (NSNs) in Canada, in compliance with the requirements of the Canadian Environmental Protection Act (CEPA). While ADW products sold broadly through the United States are now phosphate-free, manufacturers continue work to optimize the nil-P formula to improve cleaning performance that declined somewhat upon replacement of phosphate with alternatives.

The lengthy R&D process is one scenario that demonstrates the impractical timing expectation for completion of an AA in the proposed regulation. In some situations, a collaborative approach (e.g., consortium, trade association, public-private partnership) is the most efficient way in which to identify alternatives. Anti-trust requirements in the United States demand careful attention in building such a collaborative, including communication oversight by a third party. It can take three to four months to build an industry consortium before any analysis begins of a potential alternative(s) for a Chemical of Concern in a Priority Product. DTSC should incorporate flexibility into the timing expectations of the AA analysis and report submission deadlines when responsibility for the work falls to a collaborative. The logistics of the collaborative will undoubtedly slow the pace of the Stage 1 and Stage 2 analyses and necessitate expanded timelines in the final rule for a collaborative. DTSC should consider the inclusion of a provision in the final rule that allows a collaborative to form within one year of the Priority Product listing prior to the start of the AA clock.

In summary, the six and 12 month timings for the AA process in the proposed regulation are not practical or workable to account for a manufacturer’s R&D process or development of a coordinated collaborative under appropriate anti-trust auspices when an alternative is not readily available or identified. DTSC needs to expand the regulatory timeframes to a minimum of 12 months for a preliminary AA report and 24 months for a final AA report when an individual manufacturer conducts the AA, and 18 months/30 months for a collaborative approach to an AA.

- 3. Focus on Designated Chemical of Concern and Alternatives.** A single Chemical of Concern (CoC) should serve as the basis for designating a Priority Product and for the AA process. The proposed regulation provides no limitation on the number of Chemicals of Concern that could serve as the basis for designating a Priority Product, provided that collectively the Chemicals of Concern exceed the AA threshold. The comparative analysis of all potential alternatives for each Chemical of Concern in the Priority Product

would quickly become an overwhelming task and significantly compromise any chance of delivering a technologically and commercially feasible finished product that meets the consumer acceptance criteria and results in meaningful improvements in public health and environmental protection.

**4. Make consumer acceptance explicit among the factors listed in §69505.4(a)(2)(B).**

- 5. Enable a process to “declassify” a Priority Product once the AA process and subsequent regulatory response implementation result in definitive results.** We urge the Department to narrow their focus to Chemicals of Concern/Priority Product pairs that truly contribute to significant adverse public health and environmental impacts, and for which an AA would be beneficial and would improve the safety profile for public health and the environment. When definitive results have been achieved, the Department should declare success and move on to other Priority Products and not leave the “Priority Product” designation attached to a manufacturer’s product. The value chain may perceive the persistence of such a moniker as cause for de-selection or other undesirable market pressures.

**§69505.4(a)(2)(C) - Economic Impacts.** Accounting for all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered to include, among others, costs to government agency, public, waste and end-of-life management costs is so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Moreover, traditionally, it is the responsibility of the government and not the manufacturer to assess the macro/micro economic impact of regulations as it is government and not industry that is responsible for making public policy decisions. More clear and concrete criteria need to be established by which the manufacturer understands what is required to satisfy this provision. As of today, there are no well-established methodologies that are able to properly assess these types of costs to enable rigorous and meaningful comparisons across all of the A-M elements. The methods are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well-being of Californians or their environment.

**§ 69505.4(b) Comparison of the Priority Product and Alternatives.** DTSC requires disclosure in this provision of all of the product development thought process (e.g., metrics used to evaluate alternatives, weights applied to the various factors, and ultimate selection of an alternative). These decisions are value judgments, are the fundamental underpinnings of business innovation and are different company to company. The Department must ensure that this sensitive trade secret information is protected. However, assurances are lacking in the proposed regulation since §69505.5(a)(6) states, “The responsible entity shall maximize the scope of information in the AA report that can be made available to the public, while maintaining protection of legitimate trade secrets.”

## **§69505.5 - Alternatives Analysis Reports.**

### **§69505.5(i)(2)(C) and §69505.5(j)(2)(C) - Focus on Designated Chemical of Concern and Alternatives.**

Sections that reference the need for a complete list or analysis of all chemical ingredients within the Priority Product beyond the designated Chemical of Concern should be deleted. A list of other chemical ingredients in products is not necessary for the successful analysis of the Chemical of Concern and its alternatives. The intent of the statute is not ingredient disclosure for Priority Products; rather, the regulation should remain consistent with the statute and focus on assessment of the identified Chemical of Concern and its alternatives, NOT all chemicals within a product.

**§69505.5(k)(2)(A) - Compliance with law.** Within the Implementation Plan the proposed text refers to any steps necessary to ensure compliance with applicable federal, state, or local laws. This provision should be expanded to include international laws as well. Since companies operating within the U.S. often make and market products for all of North America, compliance with Mexico and Canada's requirements may also be necessary (e.g., a NSN in Canada).

**§69505.5(k)(2)(B) - Focus on Designated Chemical of Concern and Alternatives.** The manufacturer's proposed regulatory response should focus on the outcome related to the specific Chemical of Concern/Priority Product pair that drove the AA. All language relating to Priority Product's contents beyond the Chemical of Concern that was the basis for the listing should be deleted from this Article. We propose revision of the language in this section as follows:

"The implementation plan may also include the identification of any regulatory response(s) that the responsible entity wishes to propose that would best limit the exposure to, or reduce the level of adverse public health and environmental impacts posed by, ~~any the~~ **Chemical(s) of Concern, that is/are the basis for designation of a product as a Priority Product**, that will be in the selected alternative or that is in the Priority Product **above the AA threshold** if the decision resulting from the AA is to retain the Priority Product."

## **Article 6 - §69506 Regulatory Responses**

**§69506 - Regulatory Response Selection Principles.** Subdivision (a) provides that the Department shall identify and require implementation of regulatory responses that "maximize the use of alternatives of least concern, where such alternatives are technically and economically feasible." Subdivision (b) provides that in selecting regulatory responses, the Department shall give preference to responses "providing the greatest level of inherent protection." Inherent protection is defined to mean "avoidance or reduction of adverse impact or exposure that is achieved through the redesign of a product or process rather than through administrative or engineering controls."

This provision amplifies our concern expressed earlier in these comments that the proposed regulation has a clear persuasion for substitution with an acceptable alternative rather than first applying equally due consideration that a Priority Product may be completely safe as it currently exists with no change. When a manufacturer can clearly demonstrate the objective safety of a Priority Product, it is neither practical nor meaningful to expend significant people and financial resources to chase “safer” with no measurable improvements in public health or environmental protection.

**§69506.2 - AA Report Supplemental Information Requirements.** This section provides that the Department may, at any time, require a responsible entity to provide information supplementary to the final AA report for the Department to select and ensure implementation of one or more regulatory responses or to fill one or more of the information gaps identified in the final AA report. This section contains no standards by which the Department will make a decision to require supplementary information in order to evaluate an initial regulatory response and instead provides complete, arbitrary discretion to the Department. We request that the final rule contain specific standards or criteria against which DTSC can make such an information request to provide greater regulatory certainty to the regulated community. We make this same request for inclusion of standards or criteria in the final rule that will govern DTSC’s selection from the various regulatory response options listed in Article 6.

**§69506.4 - Product Information for Consumers.** This section, in summary, applies to all products going through the AA process for which implementation of the acceptable alternative has not yet occurred. The requirements of this section task a manufacturer with making substantial information available to consumers prior to exposure to any Chemical of Concern via the manufacturer’s website and through product packaging or written materials accompanying the package, or by a retailer’s action to post information in a prominent place at the point of retail display. Consumers are now accustomed to reviewing manufacturers’ websites for ingredient disclosure information, for safety information about product ingredients, to obtain a Material Safety Data Sheet (MSDS), and to review positive CPSC certification statements that attest to a product’s compliance with applicable U.S. regulations, rules, standards and/or bans. Additionally, a product label directs consumers to the manufacturer’s website or to a toll free 1-800 phone number from which consumers can obtain the same ingredient and product safety information. A requirement to add the same information on a product label about the Chemical of Concern and current, “in progress” AA status of a Priority Product is redundant with information that will be available to consumers through website or telephone access. Finally, a manufacturer has much more flexibility to add more detailed context to a website to help a consumer understand the reason for and meaning of communicated information required by this regulation than a small product label with limited space. Website communication will allow a manufacturer to also quickly respond to a change in the AA status of the product or provide updated context to consumers for any type of mandated regulatory response. In contrast, a change to product label artwork requires (at a minimum) 12 weeks to complete, which could create a situation in which the information communicated to consumers on product labels is out of step with the current regulatory status of a Priority Product in California.

DTSC relies upon their website for communication to the public of certain actions and information collected under this regulation; we ask that the Department extend this same allowance to manufacturers for consumer communication.

**§69506.8 - End of Life Management Requirements.** The California Department of Resources Recycling and Recovery (CalRecycle) is the state's leading authority on recycling, waste reduction and product reuse. As such, CalEPA authorizes CalRecycle to develop and implement end-of-life management programs, such as Extended Producer Responsibility (EPR) programs identified as "product stewardship programs" in this section of the proposed regulation. The authority provided to DTSC in this section to designate an end-of-life regulatory response is a clear example of regulatory duplication, which is prohibited by statute. At most, DTSC can propose end-of-life management actions to CalRecycle, the Department with authority to administer such waste programs in the state.

**§ 69506.9. Advancement of Green Chemistry and Green Engineering.** This section authorizes the Department to require a manufacturer to initiate a research and development project or fund a challenge grant to achieve one of four goals, all of which would supplant the manufacturer's existing product in the market. Once again, no standards are provided to indicate when DTSC could apply this regulatory response. The provision that requires funding of a challenge grant is frankly absurd unless legal protections are in place to ensure ownership of the intellectual property. The funding could directly support a third-party stakeholder who would benefit from the market exit of a manufacturer's Priority Product. It is conceivable that the recipient of the challenge grant could design a "green innovation" to specifically capture the market share of the original Priority Product. As written, there is no indication in this section that the intellectual property or other ownership rights of the resulting technology would return to the original manufacturer. If the recipient of the challenge grant were free to prosper from the "green innovation" that emerges from his/her research, DTSC would essentially have the authority under this proposed regulation to require a manufacturer to fund itself out of business. This provision basically violates every economic principle of a competitive free market. We strongly implore the Department to remove this provision in its entirety from the final rule.

**§69506.11 - Exemption from Regulatory Response Requirements.** Section 25257.1(b) of the statute provides that, "This article does not authorize the Department to supersede the regulatory authority of any other department or agency." Subdivision (c) provides that, "The Department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

This section of the proposed regulation puts the burden on the responsible entity to apply to the Department for an exemption from regulatory response requirements based on a conflict with or substantial duplication of one or more requirements of another California or federal regulatory program. Nothing in the statute imposes the burden on the responsible entity to apply for an exemption. The statute explicitly prohibits the Department from superseding, duplicating, or adopting conflicting regulations. The Legislature imposed responsibility on the Department to implement that provision.

**§69506.12. Regulatory Response Report and Notifications.** This section requires a responsible entity subject to a regulatory response to notify the retailers of the applicability of the regulatory response with respect to the product. Section 25253(b) of the statute provides that the regulations shall specify the range of regulatory responses that the Department may take following the completion of the alternatives analysis. In the proposed regulation, the Department does not designate notification to retailers as a regulatory response. Rather, the proposed regulation applies the notification requirement to a responsible entity *after* DTSC imposes a regulatory response on that entity. Nothing in the statute authorizes the Department to impose such a notification requirement after DTSC specifies a regulatory response required of the responsible entity.

#### **Article 7 - §69507 Dispute Resolution Process**

This section divides the various regulatory response procedures that appear in Article 6 into those for which formal dispute resolution procedures apply and those for which informal dispute resolution procedures apply. All final regulatory decisions and actions that DTSC employs following completion of the AA process for a Priority Product should be subject to **formal** dispute resolution procedures in the final rule. The regulated community has a right to establish an administrative record relative to an objection to a final Department regulatory action, and to escalate the objection to judicial review upon unsatisfactory administrative dispute resolution.

Similarly, the regulated community asserts that a formal dispute resolution process is needed for Department decisions made under Article 2 (Identification of Chemicals of Concern), Article 4 (Petition Process for Identification and Prioritization of Chemicals and Products) and Article 10 (Trade Secret Protection). The proposed regulation indicates that for these three Articles, a dispute would be debated in a court hearing as part of a judicial review process. A formal dispute resolution process will allow the establishment of an administrative record and opportunity to narrow scope of the dispute and exhaust administrative remedies prior to the judicial review process.

Article 7 describes a 30-day time period following “the notice or website posting of a Department decision” in which a responsible entity has the opportunity to initiate a dispute resolution process with the Department. Since 30 days is a relatively short window of time, it is critically important that the regulated community clearly understand when the “time clock” begins. For example, if the Department issues a decision via written notification, does the 30-day time period begin upon the date of the Department’s mailing or upon the date a responsible entity receives the mailing? If the Department will post decisions on their website, will there be some sort of alert to the regulated community to look for new information on the DTSC website? Section 69507.6(b)(1) shows yet another example where more specificity is needed – what sort of timeline can a responsible entity expect for compliance when the Department responds to a Request for Review? The Department needs to provide these logistical details in the final rule to set clear expectations for the regulated community and to ensure responsible entities have a thorough understanding of their rights under the dispute resolution process.

Finally, we request DTSC clarify the scope and intent of the “stayed during the pendency of an administrative dispute” language in §69507(d). Are all compliance actions described under the proposed regulation stayed from the date a responsible entity initiates a dispute with the Department to the date on which the parties resolve the dispute? As an example, is a manufacturer responsible for the consumer and retailer notification obligations for a Chemical of Concern in a Priority Product during the period of dispute examination?

#### **Article 8 - §69508 Alternative Analysis Certification**

**§69508 – Certified Assessors.** Practicing, in-house company experts with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead AA projects for product development. AA is a broad process that must evaluate a number of holistic considerations for any potential chemical alternative, including impact on safety and product performance, potential interaction with other formula components, useful life, other environmental criteria, cost effectiveness, availability, commercial feasibility and consumer preference. Manufacturers invest significant R&D resources to find the right combination of chemical ingredients for consumer product formulations. In-house company experts understand the intricate R&D science invested in developing consumer product formulations, have access to a variety of available subject matter experts, and have the necessary, in-depth understanding of consumer behavior and preferences to lead the holistic AA evaluation process. In-house company experts have a wealth of “hands-on” experience with life cycle thinking and alternatives analysis and need not complete the classroom training and continuing education classes for certification, as specified in this section.

**§69508.1 – Qualifications for Accreditation Bodies.** Due to the complex nature of any AA, the availability and accessibility to a wide range of expertise in various scientific fields are instrumental to a successful accreditation body. Broad skills and knowledge are required to conduct analysis across the extremely broad spectrum of products, chemicals, evaluation factors and impacts that would need to be assessed in the AAs envisioned by this proposed regulation. We ask DTSC to include exposure assessment as an area of practice in 69508.1(a)(5) since it appears this section omitted this important field of expertise. Key technical skills beyond exposure assessment that are required to develop safe and effective products for consumer use include toxicology, environmental toxicology, chemistry, chemical engineering, microbiology. In addition, the process will require the help of those knowledgeable in finance/accounting, life cycle analysis, and consumer and clinical testing.

The accreditation body should focus on training would-be assessors as project managers. The certified assessor should only be responsible for ensuring that all expectations and requirements for the AA have been addressed and the overall AA conforms to regulatory expectations. The certified assessor should rely on subject matter experts in the various fields and disciplines to provide the necessary information on relevant factors within an AA.

## Article 10 - §69510 Trade Secret Protection

Protection for Trade Secrets and Intellectual Property is a critical concern of the regulated community as California embarks on implementation of the Green Chemistry Initiative. The statute and this proposed regulation have rightfully made trade secret protection a core component of this program, and DTSC is supported in this effort by existing California statute and regulations. However, the proposed regulation includes several elements that conflict with and/or exceed statutory authority as detailed below.

As a threshold matter, we join our industry partners in emphasizing that product formula information is a trade secret and critical part of a company's intellectual property. A product formulation can reveal the "recipe" of flagship brands that provide decades of market success for manufacturers. While we understand the public's interest in formula ingredient information, this public interest requires a careful evaluation and balance with trade secret protection in a competitive market. Disclosure of seemingly isolated pieces of information about a product formula, including ingredient chemical names, concentrations, CAS RNs, and physicochemical properties, provide key "clues" to a trained eye to unravel sophisticated formulary science in which a manufacturer made a significant R&D investment to create. Product formula disclosure will forever present a concern to consumer product manufacturers because of the very real threat of competitive surveillance. Loss of intellectual property to competition in California prevents a manufacturer from obtaining confidentiality protection for that formula anywhere else in the world. This is very problematic for a manufacturer who intends to expand in other geographies as part of an overall global market strategy. The inability to protect formula information as confidential business information as a manufacturer enters a new market can result in a subsequent quick market entry of "knock-off" products from competitors. These competitors reap the economic benefit from marketing the innovation without investing the significant R&D capital as the original manufacturer. This dynamic showcases the challenge that domestic manufacturers face in the global marketplace and the very real threat to loss of U.S. leadership in the manufacturing sector.

We fully understand our consumers' interest in the science and safety behind all of our brands that they use in their homes and around their children on a daily basis. P&G and many of our leading industry partners have made information available and easily accessible on our corporate websites for consumers interested in learning more about our product ingredients, our product safety program and our environmental stewardship commitments. We are always willing to discuss safety questions or inquiries about specific ingredient content with our consumers when they contact us, and we routinely provide full formula disclosure and MSDSs to Poison Control Centers across the nation to respond to medical emergencies. We have a very sophisticated post-market surveillance system to monitor consumer experience with all of our products and we use insights from this work to continuously improve our products to delight our consumers by touching and improving their lives. We are fully committed to ensuring the health and safety of all of our consumers and take this core responsibility very seriously when determining which information is most helpful to make available on our product labels and websites.

The public right-to-know agenda has effectively characterized consumer product manufacturers as "hiding" important information as secrets. This is an unfair characterization considering the many opportunities we

provide our consumers to learn more about our operations and the science and safety behind our brands so that they feel informed and assured during product use. However, it is true that we and our industry partners carefully balance transparency actions with the critical need to protect our confidential business information from competition in a global marketplace.

Therefore, it should come as no surprise that substantial portions of AA reports will require trade secret protection. Detailed, data-based comparisons of Chemical(s) of Concern and potential alternatives will reveal how those ingredients interact with the formula matrix to deliver desired results. This is key information that, if disclosed by DTSC as part of a public transparency focus during program implementation, will decode confidential formulary science to competitors.

We also strongly oppose the new provision in §69510.(a)(12)(f) that prevents protection of chemical identity when that information is contained in any hazard trait submission. This is unnecessary, considering that the public can interpret hazard trait information independent of a specific chemical identity, and exceeds the Department's authority under the statute. We fully support the written comments provided by the American Chemistry Council that discuss the sufficiency of generic chemical names in association with hazard trait information to meet statutory requirements and to enable an appropriate level of information to the public for understanding the safe use of chemicals.

Disclosure of proprietary raw material considerations, compositions, processes, use methods, technology, etc., will potentially impact a manufacturer's patent rights. We support the written comments of the Grocery Manufacturers Association that explain the difficulty a manufacturer will face in the new "first to file" patent landscape in the U.S. and the complications that this proposed regulation will introduce with a strong focus on public disclosure of chemical and formula information.

**§69510 - Assertion of a Claim of Trade Secret Protection.** Subdivision (a) requires an entity making a claim for trade secret protection to provide specific substantiating information. We fully support a requirement in this regulation for upfront substantiation of trade secret protection claims. We believe the Department can further strengthen this requirement in the final rule by linking responsible entities' substantiation submissions to a commitment by the Department to review them. Currently, the proposed regulation provides no discussion or assurance that DTSC will review this information. Additionally, the proposed regulation provides no direction to a manufacturer on how to assert a trade secret claim when the manufacturer is bound by a Non-Disclosure Agreement (NDA) with a raw material supplier. This is a common scenario for which the Department will need to devise and elucidate a process in the final rule. For example, will the manufacturer have the responsibility to seek approval from the raw material supplier prior to submitting a trade secret claim to DTSC? Or will DTSC submit a written request directly to the raw material supplier to release the protection of the confidential information? These are important procedural details that will guide and clearly establish expectations for the regulated community under this section.

The criteria that DTSC list in this section for proper substantiation of a trade secret claim far exceed statutory authority. Paragraphs (1) and (2) in this section are the only criteria consistent with the language of the California Uniform Trade Secrets Act “UTSA” (Civil Code sections 3426.1-3426.11). The proposed regulation exceeds statutory authority and diverges from California UTSA in requirements presented in paragraphs such as (6), the estimated value of the information to the person and the person’s competitors; (7) the estimated amount of effort and/or money expended by the person in developing the information; (8) the estimated ease or difficulty with which the information could be properly acquired or duplicated by others, including for any chemical claimed as trade secret, an explanation of why the chemical identity is not readily discoverable through reverse engineering; and (10) a description of the nature and extent of harm that would be caused if the information were made public, including an explanation of the causal relationship between disclosure and the harmful effects claimed. This is a clear example that the proposed regulation before us is not legally defensible. The final rule should not contain any substantiating criteria that exceed statutory authority or are inconsistent with California Civil Code.

Subdivision (g) provides that trade secret protection may be claimed for the identity of a chemical that is the subject of a hazard trait submission only if the claim is for a proposed alternative to a Chemical of Concern in a Priority Product, subject to certain requirements. Those requirements include demonstrating to the Department’s satisfaction the chemical is a new chemical or a new use of an existing chemical, providing the Department with sufficient health, safety, and environmental data to demonstrate that it is substantially safer than the existing Chemical of Concern of the Priority Product, and complying with the substantiation requirements of subdivision (a). This exception does not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret. Finally, the proposed regulation provides no clarification to the regulated community of what constitutes a “new use,” for which DTSC and responsible entities may have vastly different interpretations.

**§69510.1 - Department Review of Claims of Trade Secret Protection.** This section is in need of greater clarity to ensure the regulated community understands expectations. For example, §69510.1(b)(1)(D) needs to specify a minimum period of time (no less than 30 days) by which a submitter needs to provide the requested information for equitable application. Section §69510.1(b)(1)(D)(2) and §69510.1(b)(1)(D)(2)(c) need to revise the Department actions until 30 days following receipt and signature of the DTSC notification sent to submitters via certified mail, since arrival time of the certified mail to the intended recipient may vary. Additionally, both sections need to recognize that a submitter may seek judicial review by filing an action for any type of relief appropriate under the law, not just preliminary injunction or declaratory relief.

Finally, the trade secret provisions under Article 10 need to clarify that trade secret protection can extend to review and AA involvement of external certified assessors and accreditation bodies (Article 8) and audit reports containing confidential business information (Article 9).

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## GCREgs@DTSC

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**From:** Prutzman, Annie <aprutzman@bishopodowd.org>  
**Sent:** Monday, October 01, 2012 9:22 AM  
**To:** GCREgs@DTSC  
**Subject:** Toxic Substances Control

**Categories:** Comment

To Whom it May Concern:

I understand that by law, the Department of Toxic Substances Control (DTSC) is required to enact strengthened regulations for Safer Consumer Products. The purpose is to reduce the public's exposure to these chemicals and to the hazards posed by them. 1,200 toxic chemicals in consumer products that have been identified as a threat to public health. Stronger regulations of these dangerous chemicals that currently pervade our consumer products were supposed to have been enacted, according to the law passed in 2008, by January 2011. Here it is October, 2012, and your office has not done this yet! Why should the lives of my children and my grandchildren be illegally put at risk by the tardiness of your office? What is going on in your office? Have you backed down before corporate lobbyists?

These substances must be regulated and removed AS SOON AS POSSIBLE.

It is shocking that an agency that is supposed to follow the law is not doing so. DO NOT DILUTE THIS LEGAL PROTECTION! Please grow a stiffer backbone and face down the profit mongering chemical companies. The public relies on public agencies like yours to protect public health. Please do your job! The future of my children, my students, and all the people of California depends on you!

Sincerely,  
Anne Prutzman  
A California teacher

## GCREgs@DTSC

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**From:** Allan Reynolds <ajreynolds3442@sbcglobal.net>  
**Sent:** Tuesday, October 02, 2012 11:36 AM  
**To:** GCREgs@DTSC  
**Subject:** chemicals

Where's the state's backbone? The legislators passed a BIPARTISON law in 2008 regarding an agreement to protect consumers from dangerous chemicals in the products they buy. The list was to be published in January 2011. Still not published and legislators "discussing" it with chemical companies who oppose it in Oct. 2012. We're talking about public health! Are campaign payments to legislators more important ? Please BAN these chemicals in all consumer products.

No wonder the California Legislator is held in such low regard.

Julia Reynolds - a voter for 58 years

# Etta+Billie

handmade sustainable bath and body products

October 9, 2012

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

Dear Ms. Von Burg,

My name is Alana Rivera and I own a small bath and body company based in San Francisco called Etta + Billie. I am writing you to express my concern over the proposed California Green Chemistry Initiative. My company prides itself on producing natural handmade bath and body products and I am worried that the proposed legislation would negatively impact my company, along with many other small natural manufacturers and retailers. As the regulation stands, I am highly concerned about requirements to submit confidential business information, extensive paperwork, submission of potential trade secrets along with the identification process utilized to identify chemicals of concern. I truly believe that this initiative will negatively impact many businesses throughout the state of California.

I urge you to postpone the initiative until economic consequences and other concerns can be assessed and discussed.

Thank you for your time and consideration.

Best regards,



Alana Rivera  
Owner + Creator

415.297.5528  
[www.ettaandbillie.com](http://www.ettaandbillie.com)  
2615 21<sup>st</sup> Street, San Francisco, CA 94110

## GCREgs@DTSC

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**From:** Carol Rowley <sally81800@yahoo.com>  
**Sent:** Monday, October 01, 2012 6:19 PM  
**To:** GCREgs@DTSC  
**Subject:** dangerous chemicals regulations

We need the stronger rules to regulate or eliminate dangerous chemicals in products for sale in California. Please do not stand in the way of public health.

Carol J Rowley  
[REDACTED]



**RUBBER**  
manufacturers  
association

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

October 11, 2012

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

**RE: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (July 2012)**

**I. Introduction**

RMA is the national trade association representing major tire manufacturers that produce tires in the United States, including Bridgestone Americas, Inc., Continental Tire the Americas, LLC; Cooper Tire & Rubber Company; The Goodyear Tire & Rubber Company; Michelin North America, Inc.; Pirelli Tire North America; Toyo Tire Holdings of Americas Inc. and Yokohama Tire Corporation. RMA members are affected by the proposed rule because they manufacture tires, a consumer product, available for sale or placed into the stream of commerce in the state of California.

RMA offers the following comments on the July 2012 Safer Consumer Products proposed regulation and thanks the California Department of Toxic Substances Control (DTSC) in advance for consideration of these comments. Cal. Code Regs. Tit. 22, § 55 (2012). RMA urges the Department of Toxic Substances Control (DTSC) to take the time necessary to revise this regulation to make it feasible for manufacturers.

**II. RMA supports DTSC's decision to include a delisting petition process; however, we have concerns about the timing of petition determinations by DTSC**

Article 4, Section 69504, enables a person to “petition the Department to evaluate a claim that a chemical or a product that contains a chemical should be delisted as a Chemical of Concern or a Priority Product.” (69504 (a)). As with most products available for sale in California, tires contain chemicals. However, the process of manufacturing a tire involves vulcanization, which changes the chemical composition of the chemicals formulated into the tire in the initial stages of the manufacturing process. As a result, the risk for exposure to chemicals in tires is reduced or eliminated as the chemicals in tire formulations undergo a chemical reaction

during the vulcanization or heating of a tire during the manufacturing process. RMA recommends that certain consumer products, such as tires, or chemicals present in consumer products at levels that pose no meaningful risk of adverse environmental or health impacts, should be removed from the list of Chemicals of Concern (CoC) and/or the list of Priority Products. The “early off-ramp” provided in the petition process will enable the Department to focus time and resources on the Chemicals of Concern and Priority Products that pose the greatest risk to the public.

While RMA strongly supports the inclusion of the petition process to list or delist a chemical or product, we are concerned about the timing for the Department to make determinations about whether to grant or deny a petition. The proposed rule indicates that “the Department shall make its determination no later than the next regular update of the Chemicals of Concern or Priority Products list.” (69504.1(a)). However, the proposed rule specifies that the Chemicals of Concern list shall be updated “periodically,” and the Priority Products list shall be updated at least once every three years. (*See sections 69502.3(a) and 69503.4(f)*). This creates an unreasonable situation in which a manufacturer may have to complete a preliminary and final Alternatives Analysis before a determination to grant or deny the delisting petition has been made. RMA recommends that a responsible entity should not be required to complete an Alternatives Analysis until the Department has issued a notice of their decision to grant or deny the delisting petition.

### **III. How the Safer Consumer Product Proposed Rule May Impact Tires**

#### **A. Impact on National Highway Traffic Safety Administration (NHTSA) federal safety requirements**

RMA is concerned that if tires are not granted an exemption from the regulatory response requirements of the proposed rule because of conflicts with federal law, the requirements for chemical substitution could jeopardize attainment of tire safety standards established by NHTSA. Section 69506.11 specifies that a responsible entity may request and receive an exemption from the requirements of the rule if the “required or proposed regulatory response would conflict with one or more requirements of another California or federal regulatory program or an international trade agreement with the force of domestic law, in such a way that the responsible entity cannot reasonably be expected to comply with both requirements.” (§ 69506.11(b)(6)(A)). In RMA’s view, this provision provides ample justification that tires should be exempt from the regulatory requirements of the proposed rule if removing or substituting a chemical conflicts with, or prevents meeting NHTSA motor vehicle safety standards.

Further, the proposal also specifies that “if the exemption request or the Department’s granting of the exemption is based solely on... conflict with another Federal regulatory program..., the Department may require implementation of a modified regulatory response that resolves the conflict that is the basis for the exemption.” (§ 69506.11 (d)). RMA recommends that if Federal law exempts a responsible entity from the requirements of the rule, DTSC should not require the responsible entity to submit any response.

The chemical ingredients in tires are present because they impart critical functions and the composition of tires cannot be modified without great care. All RMA members make tires that are safe. Changes in tire composition could affect critical attributes such as stopping distance, tire wear, tire fuel efficiency and other safety-related components. NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet Federal Motor Vehicle Safety Standards (FMVSS). Any change in the composition of tires typically requires feasibility studies and lengthy, multiple tests to ensure that the tires continue to meet FMVSS. If the Department requires tire manufacturers to substitute a chemical ingredient in tires with an alternative, and the use of the alternative chemical jeopardizes achievement of NHTSA safety standards, tire manufacturers may not be able to comply with both the proposed regulation and federal NHTSA safety standards.

#### **B. Impact on EPA's Corporate Average Fuel Economy (CAFE) Standards**

Corporate Average Fuel Economy (CAFE) standards were enacted by Congress in 1975 to reduce energy consumption by increasing the fuel economy of cars and light trucks. CAFE standards for cars and light trucks are established by NHTSA. The U.S. Environmental Protection Agency (EPA) provides NHTSA fuel economy data which NHTSA uses to set the CAFE standards. In regard to tires, low rolling resistance is an important attribute that automobile manufacturers require to enable them to meet fuel efficiency targets under the CAFE standards. Any change in tire composition required by the proposed regulation could affect tire manufacturers' ability to produce tires that allow new automobiles to meet the CAFE standards. If a chemical substitution required under the informal draft regulation jeopardizes CAFE standards, tire manufacturers may be unable to comply with both the proposed regulation and Federal law.

#### **IV. DTSC should include a petition process with criteria that responsible entities can submit to receive additional time to complete Alternatives Analysis (AA) reports rather than the one size fits all approach in the proposed regulation**

Again, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet National Highway Transportation Safety Administration Federal Motor Vehicle Safety Standards. Unlike chemicals that are added to a product for taste, color or appearance, the chemical ingredients in tires are present to ensure the safe and reliable function of the final product. The proposed rule specifies that preliminary Alternatives Analysis reports are due 180 days after the product is listed on the final priority product list, and final Alternatives Analysis reports are due 12 months after the date the Department issues a notice of compliance for the preliminary report. (§69505.1(c)(3)). Responsible entities can request a one-time extension from the Department of up to 90 days to complete the Preliminary or Final AA. (§69505.1(d)(1)). The proposal also specifies that entities can request up to a 36 month extension to submit a final AA report if additional time is needed to conduct regulatory safety and/or performance testing on multiple alternatives. (§69505.5(k)(1)).

RMA recommends that rather than specifying the maximum extension an entity can receive to complete the Alternative Analysis reports, that the Department grant extensions based upon a petition that demonstrates the need for additional time to enable Priority Products, whose

safety and performance are regulated by other state or federal laws, to complete safety and performance testing requirements. A case specific schedule, taking into account testing and certification procedures, is necessary, rather than the one-size-fits-all approach embodied in the current proposed regulations.

Tires are highly engineered products. The time needed to assess whether there is a workable chemical substitute for an ingredient in tires varies depending on the chemical that is to be assessed for possible replacement. Each component of a tire is composed of a different rubber compound. Compounds vary depending on the function of the compound and the type of tire that contains the compound. Thus, the type of tire that contains the Chemical of Concern, the size of the tire, the type of compound in the tire and the purpose of the compound in the tire, all affect the amount of time needed to determine if there is a viable substitution. Additionally, depending on the chemical that is to be assessed for a safer alternative, it is necessary to determine the ability of the rubber processing equipment to handle the compound that contains the new chemical.

**V. The proposed Safer Consumer Products rule must include adequate protection for confidential business information**

The proposed rule fails to provide adequate protection for confidential business information (CBI) and is inconsistent with the CBI practice followed by the National Highway Traffic Safety Administration (NHTSA) and the U.S. Environmental Protection Agency (EPA) for tires and tire manufacturing. For example, the proposed rule requires that certain information, such as “a list of, and all common names for, all Chemicals of Concern known to be in the product”, be made available to the public when an alternative chemical is not selected. (§69506.4(a)(1)(C)). This provision fails to recognize that the Chemical of Concern in the priority product may be CBI. Additionally, the proposal requires manufacturers to notify DTSC if their product contains a chemical of concern, and DTSC will post on its website the list of priority products that contain the Chemical of Concern. However, this approach also fails to recognize that the presence of a Chemical of Concern in a priority product may itself be considered a trade secret.

**A. NHTSA**

RMA recommends DTSC include categorical CBI protection for ingredients in tires that are trade secrets. NHTSA provides categorical CBI protection for various classes of early warning data required to be submitted under the TREAD Act. 49 CFR Part 512 Appendix C (2003). Examples of such early warning data for which categorical CBI protection is granted include data on production numbers, consumer complaints, warranty claims, field reports and common green tire identifier information. Common green tire information includes information regarding tires that are produced to the same internal specifications but that have, or may have different external characteristics and may be sold under different tire line names. Specifically common green tire data includes information on all relevant tire lines, tire type codes, stock keeping units (SKU) numbers, brand names and brand name owners. 49 CFR 579.26(d). NHTSA has granted categorical CBI protection for all common green tire information submitted to that agency. Information on common green tires is not available to the public and cannot be

derived from any public source. Furthermore, CBI protection for this category of information is necessary because disclosure of this information would cause substantial competitive harm to tire manufacturers since it would allow competitors to know with exact certainty which tires have the same specifications even though many are sold under different tire brand names.

NHTSA based its decision to classify categories of early warning data information as confidential, on the substantial competitive harm and impairment standards of the Freedom of Information Act (FOIA) Exemption 4. See 5 U.S.C. 552(b)(4); 49 CFR Part 512 App. C (2003). FOIA Exemption 4 specifies that information should be considered confidential if the “disclosure of the information is likely to have either of the following effects: (1) impair the Government’s ability to obtain necessary information in the future; or (2) cause substantial competitive harm to the competitive position of the person from whom the information was obtained.” *National Parks & Conservation Ass’n v. Morton*, 498 F. 2d 765, 770 (D.C. Cir. 1974). See also *Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 51 (D.C. Cir. 1981). The test for whether release of the confidential information would cause substantial competitive harm is whether disclosure of the information would “likely” cause competitive harm, for whatever reasons. *McDonnell Douglas Corp v. U.S. Dept. of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004), see also *Occidental Petroleum Corp. v. SEC*, 873 F.2d 325, 341 (D.C. Cir. 1989). One essential element is that the submitter has never released the documents to the public or to any third party. See *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 877 (D.C. Cir. 1992). Companies need not show actual competitive injury to qualify for the exemption. *Niagara Mohawk Power Corp. v. U.S. Dep’t of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999); *CNA Financial Corp. v. Donovan*, 830 F.2d 1132, 1152 (D.C. Cir. 1987). Further, FOIA Exemption 4 does not involve a balancing of competitive harm to the party that provided the information to an agency against possible societal interests such as research or provisions of information to the public.

The use of categorical CBI protection by NHTSA is also warranted by the Supreme Court’s decision in *Fed. Power Comm’n v. Texaco*. The Court in this case recognized that case-by-case decisions are not required if the use of categorical rulemaking would not be detrimental to the implementation of a regulatory scheme. *Fed. Power Comm’n v. Texaco, Inc.*, 377 U.S. 33, 44 (1964) (individual hearings for thousands of individuals who apply for certificates of public convenience and necessity under the Natural Gas Act would prolong and cripple the process of regulation).

NHTSA’s decision to grant categorical CBI protection for early warning data reduced the burden on the agency and manufacturers to complete and review CBI claims. If the agency required manufacturers to submit data confidentiality requests with each quarterly early warning data submission, it would have greatly increased the burden on industry and the agency to review the requests. Furthermore, providing categorical CBI protection also helped to eliminate the possibility for inconsistent decisions on the confidentiality of data submitted.

## **B. EPA**

The U.S. EPA provides CBI protection to specific chemical descriptions under TSCA. For example, under TSCA section 14, manufacturers and processors are permitted to claim as

CBI the specific chemical identity of a particular substance in connection with the TSCA inventory reporting requirements. TSCA section 14 prohibits EPA from disclosing confidential business or financial information submitted to the Agency under a claim of confidentiality. 15 U.S.C. §2613.

Additionally, EPA's Chemical Data Reporting rule allows claims of confidentiality for chemical identity, site identity, and processing and use information. 40 CFR Part 2 and 40 CFR 711.30. CBI protection under the CDR rule is limited to data elements where their release would likely cause substantial harm to the business's competitive position.

### **C. CBI Protection for chemical ingredients in tires**

The proposed rule incorporates by reference the definition of "trade secret" in the Uniform Trade Secrets Act. Civil Code Section 3426.1(d). This definition requires that a person asserting a trade secret claim demonstrate that the information sought to be protected has economic value and that reasonable efforts have been made to maintain its confidentiality.

RMA members have a property interest in the ingredients in their tires. Ingredients in tire formulations have a recognized economic value. Tire manufacturers spend significant resources developing new tire formulations to improve performance characteristics. Tires differ not because of taste, color or appearance, but because the tire industry is always striving to achieve better performance. Protection of confidential business information is important for tire manufacturers because they are always trying to gain an advantage over their competitors. All RMA members exercise practices to ensure tire formulations are kept confidential and not revealed to the public, and therefore competitors. Public disclosure of chemical identities will make the results of these investments in tire performance available to other companies who will not have to make similar investments.

RMA recommends that DTSC include in the final SCP rule categorical CBI protection for those chemical ingredients in tires that are trade secrets. For example, under the proposed rule responsible entities are required to include in the AA reports information on the "component(s) and/or homogeneous material(s) and its/their associated component(s) that is/are the focus of the AA," and "identification of the Chemical(s) of Concern in the Priority Product that is/are the basis for the product included on the Priority Product list, and any other Chemical(s) of Concern that is/are known, or reasonably should be known based on available information, to be in the product." (§69505.5(e)(2)(3)). Rather than asserting a claim of trade secret protection each time tire manufacturers submit an AA report to the Department that includes this information, RMA recommends that DTSC categorically consider this information and all ingredients in tires that are trade secrets to be CBI. Providing categorical exemptions for trade secrets will reduce the burden on industry and the Department to submit and review claims for trade secret protection.

We also recommend that DTSC recognize that the Chemical of Concern in a Priority Product may in and of itself be a trade secret and create a confidential process for Chemicals of Concern in priority products that are considered trade secrets.

**VI. RMA recommends that the definition of Highly Durable Products be modified to include tires**

Section 69503.4 includes provisions for highly durable products, which are defined as products that meet the following criteria: (1) assembled from 100 or more manufactured components; (2) manufacturers of the product routinely prepare information intended to be provided to consumers that indicates that the product has a useful life, or an average useful life, of five or more years; and (3) the product is typically not consumed, destroyed, or discarded after a single use. (§69503.4(a)(2)(B)(3)). RMA questions DTSC's rationale for including the requirement that highly durable products must be assembled from 100 or more manufactured components. Tires are unlikely to satisfy the first requirement for classification as a highly durable product as they are not manufactured from 100 or more manufactured components. In order to include tires in the definition of highly durable goods, we ask that DTSC reduce or delete the number of manufactured components requirement.

The proposal limits the number of AA's a responsible entity can complete for Chemicals of Concern/ Priority Product combinations for highly durable products. Specifically, the proposal states that for listed highly durable products, "the Department shall specify no more than 10 components and/or homogenous materials per product every 3 years." (§69503.4(a)(2)(B)(2)). In the Initial Statement of Reasons document, DTSC indicates that it limited the number of AA's that must be completed every 3 years to "allow manufacturers of durable products, such as the automobile industry, that have longer product development time frames to conduct the Alternatives Analysis." (Initial Statement of Reasons, R-2011-02, at 101). Further, the Department reasoned that "by limiting the components or homogeneous materials in the components as well as when the specified durable product is subject to an Alternatives Analysis, manufacturers are provided adequate time to address the durability requirements of the product." Id.

Like automobiles, tires must meet Federal Motor Vehicle Safety Standards (FMVSS). As mentioned previously in these comments, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet FMVSS. Changes in tire composition could affect the stopping distance of tires, tire wear, tire fuel efficiency standards and possibly other safety-related factors. Any change in the composition of tires typically requires feasibility studies and multiple tests to ensure that the tires continue to meet FMVSS. We request that DTSC amend the definition of highly durable products to allow tires to be classified as highly durable products in order to provide the tire manufacturing industry with "adequate time to address the durability requirements of the product." Id.

**VII. RMA recommends that DTSC include a workable definition of the Alternatives Analysis Threshold Exemption that is based on actual exposure and risk**

Section 69503.5 stipulates that "the Department shall specify an alternative analysis threshold for each Chemical of Concern that is a basis for the product being listed as a Priority Product." (§69503.5(c)). Past drafts of the Safer Consumer Product rule included a *de minimis* exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1%

for all other chemicals. We recommend that DTSC include an Alternatives Analysis Threshold Exemption with a default level of 0.01% for chemicals with one of nine hazard traits, and 0.1% for all other chemicals and provide DTSC the discretion to set lower or higher Alternative Analysis Threshold Exemptions as needed.

RMA recommends that the final rule acknowledge that all chemicals do not pose the same risk. Failure to include a default Alternatives Analysis Threshold Exemption or a screen that will allow DTSC to focus on Priority Products that pose the greatest risk, will slow down the risk reduction process which is envisioned by the statute (AB1879). We strongly urge DTSC to include a default Alternatives Analysis Threshold Exemption in the final rule.

### **VIII. Alternatives Analysis Report**

#### **A. RMA supports the requirement in the first stage of the Alternatives Analysis to identify the function, performance, and legal requirements associated with the Priority Products that must be met by the alternatives considered.**

In the first stage of the AA, “the responsible entity shall identify the function, performance, and legal requirements associated with the Priority Product that must be met by the alternatives being considered.” (§69505.3(b)(1)). In previous comments filed on past drafts of the Safer Consumer Products regulation, RMA expressed concern that prior drafts failed to adequately take into account differences between chemicals that are added for style, attractiveness or other nonessential purposes, and chemicals that are included in complex mixtures (such as tires) and whose presence in the product is necessary to impart an essential function (such as stopping distance, tire wear, and fuel economy of the tire). RMA strongly supports the inclusion of this provision that requires responsible entities to identify the function of the CoC in meeting the Priority Product’s function in determining whether an alternative chemical is feasible.

#### **B. RMA does not support the possible requirement to conduct research and development projects or fund a green chemistry challenge grant for priority products where no alternative chemical is selected because it is essentially a tax on manufacturers.**

After completing the first stage of the AA, if a responsible entity determines there is no functionally acceptable alternative chemical, the responsible entity may submit an abridged AA. (§69505.2(b)). However, even if the entity demonstrates that no viable alternative chemical currently exists, it may be required to conduct a research and development project or fund a green chemistry challenge grant for the product. (§69506.9). This essentially “taxes” a manufacturer even when there is a no substitute for the Chemical of Concern.

Section 69506.9 specifies that the requirement to initiate a research and development project or fund a challenge grant is to: “(a) Design a safer alternative to the Priority Product; (b) Improve the performance of a safer alternative to the Priority Product; (c) Decrease the cost of the safer alternative to the Priority Product; and/or (d) Increase the market penetration of a safer alternative to the Priority Product.” *Id.* This raises significant confidentiality issues in an

industry (such as the tire industry) where the products have important and significant chemistry-based differences. Developing a one-size-fits-all substitute would be unworkable for RMA members.

**IX. DTSC should substantiate the need for information required to be submitted under the proposed rule**

Responsible entities are required to submit a vast amount of information in Preliminary and Final AA Reports. (§69505.5). For example, responsible entities are required to submit information on “the proximity of the place(s) of product manufacture to one or more source(s) of virgin or recycled materials that directly or indirectly influences the type and/or amount of Chemicals(s) of Concern in the Priority Product.” (§69505.5(d)(5)). DTSC has not substantiated the need for information pertaining to a manufacturer’s proximity to recycled materials that influence the type and/or amount of a CoC in the Priority Product. Reporting requirements under the proposed rule will require significant resources and time from DTSC and the companies that submit the data. RMA recommends that the reporting burdens under the proposal be justified by a specific and clearly demonstrated need for the information.

**X. DTSC should not determine whether safer alternatives exist for the chemical ingredients in tires**

As part of the Alternatives Analysis, a responsible entity shall include retaining the Chemical of Concern in the Priority Product as one of the alternatives being considered. (§69505.4(a)(1)(B)). However, despite the determination that a technically and economically feasible alternative chemical does not exist, DTSC may determine and notify a responsible entity that it believes there is an alternative chemical that is “safer”. (§69506.6(b)). Responsible entities that receive this notification shall cease to place the product into the stream of commerce in California within one year. DTSC can also ban the product from being sold in California.

DTSC should not specify which chemical ingredients should be used in tires. All RMA member make tires that are safe. As discussed above, NHTSA requires that all tire manufacturers self-certify that tires sold in the U.S. meet National Highway Traffic Safety Administration Federal Motor Vehicle Safety Standards. Should DTSC require tire manufacturers to use an alternative chemical that the industry has determined through an Alternatives Analysis is not technically or economically feasible, the tire manufacturing industry will be unable to comply with the proposed regulation and federal law at the same time. RMA recommends that where safety and performance of a consumer product are regulated by other Federal or State agencies, DTSC should not be empowered to determine and/or require that a safer alternative chemical should be used in the Priority Product.

**XI. RMA recommends that DTSC not expand the end-of-life management requirements**

Section 69506.8 specifies that end-of-life management is required for Priority Products for “which an alternative is not selected, that is sold or otherwise made available to consumers as a finished product and is required to be managed as a hazardous waste in California at the end of its useful life.” Tires are not managed as hazardous waste in California, so assuming tires are

selected as a Priority Product, an end-of-life management program should not be required for tires.

RMA and its members have engaged in a sustainable end-of-life management program for tires without the necessity of regulation. For more than two decades, the tire manufacturing industry has developed a voluntary post-consumer product recycling program that has resulted in approximately 90% of its product being recycled.<sup>1</sup> RMA does not support mandatory end-of-life management requirements for tires. Any end-of-life management requirements for tires will disrupt the established, voluntary, scrap tire market.

**XII. RMA supports the inclusion of the Safer Consumer Products Partner Recognition List**

The Safer Consumer Products Partner Recognition List may enable DTSC to fulfill the intent of the statute in a more appropriate manner by eliminating the need to focus time and resources on products that pose no risk. Section 69501.4(d) specifies that persons may voluntarily complete an AA on a consumer product that has not been listed as a Priority Product, and/or voluntarily provide information that is helpful to the Department in implementing this chapter. Further, the Department shall maintain on its website a SCP Partner Recognition List that identifies persons who have voluntarily provided information to DTSC that advances the quest for safer consumer products.

While RMA supports the inclusion of the opportunity to submit an AA to DTSC before a product is listed as a Priority Product, we question what specific information would be most helpful to the Department in advancing the “quest for safer consumer products”. Additionally, we ask that the Department specify that manufacturers can be placed on the Safer Consumer Products Partner Recognition List even when an AA report specifies that no economically or technically feasible alternative exists.

**XIII. RMA believes that responsible entities should not face penalties of perjury for errors made on information submitted to DTSC**

Section 69501.3(c) specifies that all information submitted to DTSC by a responsible entity is submitted under penalty of perjury. Specifically the proposed rule requires a company officer or owner to certify as follows: “under penalty of perjury... this document and all attachments were prepared or compiled under my direction or supervision to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person(s) directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that submitting false information or statements is a punishable offense.” Id. Nothing in the statute confers authority on DTSC to require that an owner or an officer of a company must certify under penalty of perjury that the substantiating information is correct. This requirement results in the

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<sup>1</sup> See RMA Scrap Tire Markets Internet page, available at <[http://www.rma.org/scrap\\_tires/scrap\\_tire\\_markets](http://www.rma.org/scrap_tires/scrap_tire_markets)> and RMA, Scrap Tire Markets in the United States 9th Biennial Report (May 2009), available at <<http://www.rma.org/getfile.cfm?ID=985&type=publication>>.

potential imposition of a criminal penalty if a question is raised about the accuracy of the information. DTSC lacks the authority to create circumstances that give rise to a criminal penalty; only the California Legislature has this authority.

RMA recommends that DTSC require responsible entities to certify that the submitted information has been completed in compliance with the requirements of this rule and that confidentiality claims are true and correct. EPA uses this certification language in the TSCA Inventory Update Reporting Modifications; Chemical Data Reporting final rule (CDR final rule). 76 Fed. Reg. at 50816. Specifically the CDR final rule specifies that “the authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the Form U are true and correct. The certification must be signed and dated by the authorized official for the submitter company, and provide that person’s name, official title, and e-mail address.” Id. at 50872.

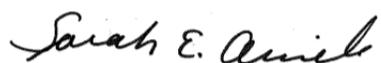
#### **XIV. Conclusion**

The tire industry supports sustainable production and the development of methods to reduce the risks of exposure to chemicals used in products. However, the proposed regulation grants virtually unreviewable authority to DTSC to require substitution of chemicals in tires. This threatens tire manufacturers ability to meet and comply with Federal Motor Vehicle Safety Standards and the requirements of the July 2012 proposed Safer Consumer Products regulation.

As written, the informal draft regulation cannot be applied to tires in any feasible way. RMA recommends that DTSC revise the regulation to: (1) ensure that DTSC responds to petitions to delist a Priority Product before a responsible entity must complete an Alternatives Analysis; (2) harmonize the proposed regulation to enable tire manufacturers to comply with both Federal Motor Vehicle Safety Standards and the proposed regulation; (3) provide a process that enables tire manufacturers to demonstrate the need for additional time to complete the Alternatives Analysis process in order to conduct feasibility, safety, and performance testing on alternatives; and (4) provide a categorical CBI exemption for ingredients in tires.

RMA again thanks the California Department of Toxic Substances Control for this opportunity to comment on the informal draft regulation. Please contact me at (202) 682-4836 if you have questions or require additional information.

Respectfully Submitted,



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