



## San Benito County Integrated Waste Management Department / Regional Agency

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Normandy A. Rose, Director  
Lisa Jensen, Recycling & Resource Recovery Coordinator

October 11, 2012

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

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

Dear Director Raphael:

The San Benito County Integrated Waste Management Regional Agency has long been a supporter of the development of the Green Chemistry program in California. As a local government agency we have anxiously awaited the implementation of this program as we recognize the multi-disciplinary benefits that it will provide: elimination of pollutants at the source thereby removing the need for costly pre-treatment to the POTW and fewer materials to handle through Small Quantity Generator (SGQ) and Household Hazardous Waste (HHW) programs. These actions ultimately reduce costs for both the recipient business and generating industry, as well as local government HHW programs.

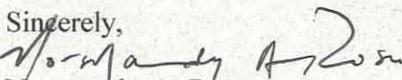
It is unfortunate that many of the manufacturers of these targeted materials provide non-toxic products to our European Union neighbors but balk at providing the same courtesy to the United States in general and California in particular. It is equally unfortunate that product packaging continues and has expanded to include hazardous constituents.

We would like to go on record as stating that we generally support the proposed regulation but would respectfully request that you consider two significant revisions that have been vetted by the California Product Stewardship Council (CPSC) of which we are a member:

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

We know you recognize that it past time for California to act on implementing a Green Chemistry program. We have a unique opportunity to become a world leader in creating producer responsibility systems that drive and incentivize green/cradle to cradle design. California needs to return to its rightful of leadership in the field of sustainability.

Sincerely,

  
Normandy A. Rose  
Director

COUNTY OF SANTA BARBARA  
PUBLIC WORKS DEPARTMENT  
123 East Anapamu Street  
Santa Barbara, CA 93101  
805\568-3000 FAX 805\568-3019



SCOTT D. MCGOLPIN  
Director

October 10, 2012

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

**RE: Comments on Draft Regulations for Safer Consumer Products**

Dear Director Raphael:

The County of Santa Barbara strongly supports the development of a Green Chemistry program in California to identify "Chemicals of Concern" and reduce toxic chemicals at the source. The stream of products requiring special end-of-life management is growing every year, and local government household hazardous waste (HHW) collection programs bear the burden of managing them at a substantial cost. As such, we are very supportive of California's Safer Consumer Products Program that will promote the re-design of these problem products.

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

- (1) End of life management requirements – Proposed stewardship plans (page 58, starting on line 1) should be posted on the DTSC website, and DTSC should invite input from local government agencies and the public prior to approving the plans.
- (2) Municipality costs – DTSC should add "cost to municipalities" as a prioritization factor in determining which chemicals will first undergo an alternatives analysis. By removing problem chemicals from products, HHW programs will have fewer products to manage, resulting in significant cost savings to taxpayers and ratepayers. Statewide, these cost savings could equal tens of millions of dollars.

We look forward to DTSC's continued leadership in making California a world leader in producer responsibility systems that drive green design and reduce the use of hazardous materials.

Sincerely,

Mark Schleich  
Deputy Director, Public Works Department

AA/EEO Employer

## GCREgs@DTSC

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**From:** Keemo Jeong <keemo77@naver.com>  
**Sent:** Thursday, October 11, 2012 8:32 AM  
**To:** GCREgs@DTSC  
**Cc:** Madriago, Odette@DTSC; Wong, Jeff@DTSC; youngil2.kim@skhynix.com; seungjong.ko@skhynix.com; keemo.jeong@skhynix.com; steve@ksia.or.kr  
**Subject:** Comments of the SIA in Korea on Proposed Safer Consumer Products Regulations, California Regulatory

Dear Ms. Von Burg:

On behalf of the Semiconductor Industry Association of Korea(KSIA), we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxics Substances Control (DTSC), published in the California Regulatory Notice Register (file number Z-2012-0717-04) on July 27, 2012.

SIA in Korea is the trade association of the semiconductor industry in Korea. More information about our organization can be found at <https://www.ksia.or.kr/renewal/eng/>.

We are writing in support of the comments filed on October 11, 2012 by several technology associations based in the United States. The organizations are the Information Technology Industry Council (ITIC), TechAmerica, the Consumer Electronics Association (CEA), and the Semiconductor Industry Association (SIA) in the United States. The members of SIA in Korea have reviewed the comments of these other technology associations and we endorse these comments. As discussed in detail in those comments, we believe that these proposed regulations set forth a burdensome and subjective regulatory scheme that will be infeasible and expensive for manufactured products such as semiconductors. In addition, we believe that some requirements may represent a technical barrier to trade (TBT) under the rules of the World Trade Organization (WTO), and could result in the disclosure of trade secrets and confidential business information (CBI).

We appreciate the opportunity to provide input on these proposed regulations.

Sincerely,  
Keemo Jeong

\*\*\*\*\*

SK Hynix, ESH R&D Centre

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October 11, 2012

Debbie Raphael  
Director, Dept. of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806

**Re: Safer Consumer Products Draft Regulations**

Dear Director Raphael:

Sierra Club California strongly supports the Department of Toxic Substances Control (DTSC) proposed regulations on Safer Consumer Products (SCP) and urges its swift adoption. California needs protection from dangerous exposure to toxic chemicals in products and must not delay such important environmental and public health safeguards. We appreciate the time, efforts and careful consideration that you and your staff have put into drafting the regulation.

There are more than 100,000 chemicals currently in commerce and more than 2,000 new chemicals are added each year. Existing laws do not adequately protect the environment and consumers from unnecessary exposure to toxic levels of these chemicals. According to the Berkeley Center for Green Chemistry, health care costs for California's children and workers from chemical and pollution-related diseases exceed \$2 billion per year. Preventable chronic illnesses, developmental and behavioral disorders such as ADHD, infertility, cancer and birth defects are linked to exposure to harmful toxins in products. The harm does not just end with consumers. Dangerous substances from products will make their way to the environment where they pollute our water and harm wildlife. Local governments are usually tasked with water treatment and cleanup efforts that costs taxpayers billions of dollars each year.

Sierra Club California strongly supported the 2008 enabling legislation that required the SCP regulation. The legislation aimed to address single-chemical ban proposals at the legislature and received support and collaboration from environmental groups, public health advocates, and the chemical industry. When it was enacted, we were confident that our collaboration would result in smart rules and that the industry would continue to support the effort. Since then, there have been delays and industry efforts to weaken the law. Finally, after four years of regulatory process, we are about to see the bill implemented through the new SCP regulations. We anticipate that there will be no further delays that would require us to seek further legislative action to ensure that consumers and the environment are protected from toxics in products.

We commend DTSC staff for the many positive aspects in the latest iteration of the regulations and support the department's plan to move forward with implementation. The regulations are scientifically sound and are consistent with the feedback from that DTSC has received from its science panel.

Below is a list of positive highlights and suggested amendments to strengthen the regulation.

**Sierra Club California strongly supports the following elements in the regulation:**

1. A comprehensive list of Chemicals of Concern (COC). The regulation currently includes a list of 1300 COCs drawn from existing lists prepared by respected government, scientific and regulatory bodies that identify chemicals that are known to be harmful. The list provides the necessary signal to the market that the state expects stewardship for hazardous chemicals. A comprehensive list will also help avoid regrettable substitutions. However, for the list to be most effective, it must also include chemicals hazardous to the environment in addition to those posing public health threats.
2. There is noteworthy effort in capturing environmental endpoints and impacts. We appreciate the focus on the natural environment in the definitions of environmental impact. Capturing environmental endpoints such as wildlife, wetlands, and watersheds or larger ecosystems will ensure that we address products that contain chemicals harmful to the natural environment.
3. End-of-life Product Management. The automatic requirements for end-of-life management are crucial to ensure proper handling of priority products at the end of their useful life. These requirements will also encourage manufacturers to incorporate innovation into their designs to create greener products.
4. Regulatory Response Selection Principles. By including the "Regulatory Response Selection Principles" in the regulatory response process, the Department can support innovation and alternatives that promote protection for the environment and human health. We strongly support criteria that emphasize alternatives that will achieve the best results in limiting impact, exposure and pollution and do so in a timely manner.
5. Assessor Certification. The proposed third-party assessor certification program will help ensure quality information received from manufacturers and responsible parties. This will also enhance the likelihood of acceptable and unbiased alternative assessments.

Sierra Club California urges that the following amendments be made to improve the proposed regulation.

1. Increase the number of products addressed within the first three years of implementation (§ 69503.4). Implementation of the regulations should be robust to meet expectations established by the enabling legislation, retain public support, and protect the environment and public health. The current plan to address no more

than five priority products during the initial phase of implementation suggests this is a pilot program, rather than the protective program the legislature intended. A ramp up during the first year of implementation could be reasonably expected, but after that first year, the program should be fully implemented and address more products. We urge DTSC to revisit its plan for implementation to help avoid the need for additional legislative action.

2. Improve the public involvement process. The implementation process should be transparent, and offer more information and opportunities for the public to provide comments before key decisions are made. Below are some specific suggestions:
  - a) Public input should be solicited prior to initial release of Priority Product List and Work Plan. The Department should also seek comments on the Alternative Assessment (AA) Work Plans in parallel with DTSC review. Comment periods should be 45 days minimum.
  - b) In the list of documents that DTSC will make available online, all public comments should be included. § 69501.5 should be modified to include public comments on work plans (referenced on page 39, line 2 to 3).
  - c) Additionally, the Department should revise the wording in § 69505.5, page 47 line 14, from “presented in matrix” to “*summarized* in matrix”. In its present form, a matrix will not provide enough information to the public and stakeholders therefore should only be used as a way to summarize key points and additional information to be linked.
3. Problematic omission of the Water Board/EPA 303(d) list from the List of Lists (§ 69502.2). The list of chemicals of concern does not include the most common environmental contaminants that pollute our water and harm habitat. By adding the 303(d) list, DTSC will ensure the regulations capture those pollutants. The Water Board/EPA 303(d) list is the list of “impaired” water bodies and the chemicals impairing them in the state of California. It is congruent with the Department’s Statutory Intent and Requirement as it is reliable and readily available information that is scientifically sound. Even though the list appears under the definition of “adverse water quality impacts”, it also needs to be added to the List of Lists and the chemicals to the list of COC.
4. Remove incentives to hide data (§ 69503.2). Prioritizing products based on availability of information will incentivize the practice of hiding data and discourage manufacturers and responsible parties from publishing scientific studies on chemicals.
5. Exposure pathways must be identified in the Preliminary Alternative Assessment Report (§ 69505.5). A major reason consumer products pollute the environment is that manufacturers are unaware of environmental exposure pathways. DTSC should require the elements of § 69505.5(g) to be included in the Preliminary AA report work plan.

6. Need to increase the number of components in highly durable products regulated every three years (§ 69503.4). As currently written, DTSC will only focus on 10 components in each manufactured product that is considered highly durable every three years. This set maximum will further delay implementation and weaken the program. A durable product, as noted in the regulation, could contain 100 or more components and each of those components can represent a pollution source. Some products may have thousands of components and by addressing only 10 components every three years, it will take decades for safer alternatives to appear on the market. We recommend that DTSC set a maximum percentage of components in each manufactured product that can be regulated every three years as a compromise that will protect manufacturers, consumers and the environment.
7. Timeline should be tightened to reduce the amount of time from now until safer products are on shelves (§ 69503.4). The level of flexibility in § 69503.4 might result in delays. Preliminary AA Reports should not be submitted more than 180 days after a product is listed as a Priority Product except in very rare circumstances. Safer products need to be available to consumers soon and not years from now. We recommend that DTSC establish narrow criteria for allowing extensions of the timeframes specified in the regulations under exceptional circumstances.
8. More consideration needed for environmental impact and costs to other agencies, organizations and companies in the Regulatory Response Selection Principles (§ 69506).
  - a) When identifying administrative and other costs associated with safer consumer products, DTSC should also take into consideration the burden placed on other government agencies and organizations such as the Department of Parks and Recreation, the Department of Fish and Game, non-profit land stewardship organizations, and companies that manage wastes. On page 52 lines 22 to 23 should include “*other government agencies, non-profit organizations, other private businesses*”.
  - b) In addition, the negative impacts to the natural environment should be considered throughout the regulation and especially as part of the Regulatory Response Selection Principles. The principles were set up to provide guidelines on how DTSC will select regulatory responses therefore it would be important for the Department to stress environmental impact as part of the list of principles. On page 52 lines 24 to 25, the wording should be modified to read “upon sensitive subpopulations *and ecosystems*”.
9. The Regulatory Response Selection Principles (§ 69506) should specify that the Department will seek timely protection for human health and the environment. As mentioned in our previous points, timeline is a concern for Sierra Club California. We would like to see safer consumer products be placed in commerce as soon as possible before worse pollution and more illnesses occur. This sentiment needs to be conveyed in § 69506 as one of the main guiding principles for selecting regulatory responses.

10. End-of-life management plan needs input prior to approval (§ 69506.8). We urge that DTSC solicit public comments on proposed product stewardship plans to ensure transparency and effective waste management from manufacturers. This should be done prior to approving the plan and all information should be posted online and available to the public.
  
11. Remove exemptions for “historic products” (§ 69501.1). According to the Initial Statement of Reason, DTSC clarified that “historic products” will be exempted from the regulations because even though they still exist, they are no longer in production. This blanket exemption should not be made without further evaluation on public and environmental health threats from the product, part of the product and its components. The Department should strike this definition out of the regulation and make these considerations when developing product-specific regulatory responses, using the established principles.

Thank you for the opportunity to provide these comments. We strongly support the regulations and feel that they will move us in the right path to safer consumer products.

Sincerely,

A handwritten signature in cursive script, appearing to read "Annie Pham", with a long horizontal flourish extending to the right.

Annie Pham  
Policy Advocate

## GCREgs@DTSC

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**From:** Margaret Sjostrand <marstrand2000@yahoo.com>  
**Sent:** Thursday, October 04, 2012 8:11 PM  
**To:** GCREgs@DTSC  
**Subject:** Protect consumers

This is to urge California legislators to act to protect consumers from dangerous chemicals in the products we buy. This is a moral decision which is essential for the health of all Americans. It is inconceivable to me that our elected officials would even hesitate to establish the strongest of rules necessary to accomplish safety for all. There are already too many toxic chemicals in our environment. Remember, constituents will be watching!

Thank you,

Margaret Sjostrand

## GCREgs@DTSC

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**From:** Andrea Snow <ajsnow@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 11:14 AM  
**To:** GCREgs@DTSC  
**Subject:** regulations

**Categories:** Comment

If I understand it, regulations protecting consumers from dangerous chemicals were supposed to be strengthened by January 2011. It's taken this long for our legislators to come up with an agreement -- FINALLY -- but one that is now threatened by the powerful chemical industry. Don't let the chemical industry derail public health. The DTSC must finish writing regulations and enact them!

Thank you,  
Andrea Snow



October 11, 2012

**BY E-MAIL (gcregs@dtsc.ca.gov) & U.S. Mail**

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

Re: Comments on Draft Regulations (Released July 27, 2012)

Dear Ms. Von Burg:

On behalf of one of our clients, this letter provides comments on the draft regulations ("Proposed Regulations") known as the Safer Consumer Products regulations (proposed 22 CCR §§ 69501 - 69511). The comments are ordered according to section.

*The Regulations Should Respect the Statutory Limitation of  
Consumer Products and Should Not Cover All Products.*

As written, the proposed regulations make every product a consumer product. This is an improper and unauthorized extension of the enabling legislation. This improper extension of the law to include products other than consumer products is the result of "person" being defined to extend beyond natural persons. Person should be defined as natural persons; it should not include corporations and other entities.

In November 2010 and December 2011, we submitted comments to the then proposed regulations requesting that the Department narrow the definition of "person" because it was overbroad and inconsistent with the enabling legislation. However, the definition of "person" remains the same in the Proposed Regulations as it did in 2010. Namely, proposed section 69501.1(a)(44) defines "person" by incorporating Health and Safety Code section 25118. Section 25118 defines person to mean not only an individual, but also a "trust, firm, joint stock company, association, and corporation, including . . . the state . . . and the federal government or any department thereof."

There are at least three reasons why the state should revise the draft regulations to define "person" in the Proposed Regulations as an individual rather than the vastly broader definition presently offered. First, the word "person" should be interpreted in context, not in isolation, according to standard California rules of statutory interpretation. The context of "person" as a user of a "consumer product" in Health & Safety Code section 25251(e) strongly favors defining person as an individual, not a corporation or the federal government.

Second, the current draft definition would absurdly define anything in the state as a consumer product, and absurd consequences are a strong indicator that language has extended beyond the Legislature's intent. The Department's proposal would make an aircraft carrier (97,000 tons), the Capitol Building, a freight train and an industrial forklift all consumer products. Because the federal government, the State, and companies that operate freight trains and forklifts all are "persons" and "use" large navy ships, the Capitol and freight trains, all of these things would be "consumer products" under the State's proposed definition. This is turning the title of the legislation and the key provision defining its scope completely upside down. Similarly, it is absurd to think of a fork lift as a "consumer product." Consumer products should be defined as things that *people* use when they are acting as consumers, not all things under the sun, and not things that are obviously industrial products.

Third, if the Department's currently proposed definition of person were adopted, it would expand the definition of "consumer product" to mean any product whatsoever, and thus would render the word "consumer" in the statute not only meaningless, but deceptive. Each word in a statute should be given meaning and the Initial Statement of Reasons fails to explain how the Department has given meaning to the word "consumer" in this statute.

The Initial Statement of Reasons ("ISR") explains the Department's choice of an expansive definition of "person" as follows: "This definition is consistent with other uses in programs administered by DTSC." (ISR at 31). No such program is identified, however, and we are not aware of any other program that DTSC administers relating to consumer products. Indeed, the definition of person that DTSC proposes to incorporate is from the original 1972 California hazardous waste control law that focused on controlling the generation, handling, storage, transport and disposal of hazardous waste -- a very different context from how to define the reach of a "consumer product" law.

#### *Food Packaging Should Be Excluded*

The regulations should expressly exclude food packaging from the green chemistry program. We request that Proposed Regulations section 69501(b) (where the exemptions are now located) be revised to include such an exemption. Alternatively, we request that the Department determine, before the regulations become effective, that FDA's regulation of food packaging materials addresses the matters noted in section 69503.2(a)(3) such that the proposed regulations would not apply to food packaging materials.

#### *Trade Secret Protection*

Overall, the provisions for protecting trade secrets are unreasonably costly to follow and exclude from protection altogether certain currently protected information.

Proposed section 69510(a) only should require that items one through four be specified in the first instance, with a statement that adequate measures to restrict access have been taken (without the need to detail such measures). It is not reasonable to require further substantiation for most of the information that will be submitted to DTSC and in circumstances where no controversy concerning the applicability of the trade secret protection applies. Sections 5 through 10 of proposed section 69510(a) are unduly costly and not necessary in the first instance. In the event of an important controversy, it is possible that the information called for in sections 5 through 10 would be cost justified, but that determination should be made on a case-by-case basis by DTSC. Moreover, fully complying with these provisions likely will

require the generation and sharing with DTSC of further trade secret information and provide undue burden on entities or persons that submit information. Lower cost alternatives should be thoroughly explored for this provision, and have not yet been so explored or detailed in the Initial Statement of Reasons.

The requirement in proposed section 69510(b) of automatically providing a redacted version of a trade secret document is not reasonable or cost justified. The regulations potentially call for substantial document submissions. Redacting substantial submissions can become very expensive very quickly. Again, the need to redact should be identified on a document-specific and context-specific basis where needed, not generally applicable to all documents submitted.

Section 69510(f) should not be adopted. This provision is not authorized by the enacting legislation. The Initial Statement of Reasons claims that section 69510(f) implements section 25257(f) of the Health and Safety Code. This claim, however, is not accurate. Section 25257(f) simply excludes hazardous trait submissions from the specific procedures governing trade secrets found in section 25257, it does not repeal all of the general protections of trade secret law in California as they relate to hazardous trait submissions. Even if section 69510(f) were to be found to be authorized by statute, which we dispute ever could be the case, it is unduly burdensome and a substantially less restrictive alternative should be utilized in order to better protect trade secrets. Since proposed section 69510(f) should not be adopted and is not authorized by the enacting legislation, sections 69510(g) and 69510(h) also should not be adopted.

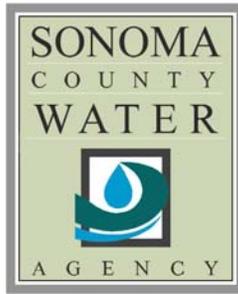
Section 69510.1 should contain a provision allowing for the return of information to the submitter that has been claimed to be trade secret and that the submitter contends is trade secret information if California determines that it cannot agree with the submitter's claim. In order to encourage proper submissions, and in order to allow a company to opt out of sales in California if necessary to protect information recognized as trade secret information outside of California, California should allow for the return of information when California disagrees that a claim of trade secret protection is valid.

Sincerely,



Gary M. Roberts

GMR:ar



October 11, 2012

**VIA ELECTRONIC MAIL**

gcregs@dtsc.ca.gov

Director Debbie Raphael  
California Department of Toxic Substances Control  
Office of Legislation and Regulatory Policy  
P. O. Box 806  
Sacramento, CA 95812-0806

**SUBJECT: DRAFT REGULATIONS FOR SAFER CONSUMER PRODUCT REGULATIONS**

Dear Director Raphael:

I am writing to indicate our support for implementation of Safer Consumer Product Regulations now under consideration by the Department of Toxic Substances Control and to urge you to consider modifying the proposed regulations in order to:

- (1) Require that proposed stewardship plans be posted on the DTSC website with an opportunity for comment by local government agencies and other parties.
- (2) Consideration of the cost to municipalities as a prioritization factor. Local agencies that manage these contaminants in waste streams and sanitation systems could realize significant future cost savings by reducing the volume of these substances in commerce.

As a wholesale water provider and operator of municipal wastewater treatment systems holding NPDES permits we are well aware of the potential future costs for removal of trace contaminants from water and wastewater. Advancements in analytical technology often lead to new permit requirements that bring ever lower discharge limits and add new compounds to the list of those that must be measured, monitored and removed from water and wastewater streams.

The most cost effective way to remove these substances from source water and from waste water flows is to reduce their introduction in to the environment on the product side. We strongly support your effort to achieve this goal with the proposed regulations.

California has always led the nation in innovative measures that lead to improved public health and environmental protection and the work your department is doing to develop these new regulations will continue and advance that tradition.

Thank you for your work on this and for the opportunity to submit these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Grant Davis". The signature is stylized and cursive.

Grant Davis,  
General Manager

**From:** Steve McDonald <SteveM@sema.org>  
**Sent:** Monday, September 10, 2012 1:18 PM  
**To:** GCREgs@DTSC  
**Subject:** SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2100-02, Office of Administrative Law Notice File Number: Z-2012-0717-04

**Categories:** Comment

September 10, 2012

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

**RE: SAFER CONSUMER PRODUCT ALTERNATIVES; Department Reference Number: R-2100-02, Office of Administrative Law Notice File Number: Z-2012-0717-04**

The Specialty Equipment Market Association (SEMA) is pleased to provide comments relative to the Department of Toxic Substance Control's proposed addition of chapter 55 to division 4.5 of Title 22, California Code of Regulations. This proposal seeks to adopt regulations to establish a process to identify, prioritize and evaluate those chemicals, and their alternatives, in consumer products that may be considered chemicals of concern.

SEMA is a trade association headquartered in Diamond Bar, California and made up of more than 6,500 mostly small businesses in California and around the country that manufacture, rebuild, distribute and retail parts and accessories for motor vehicles. The products manufactured by our member companies include functional, restoration, performance and styling enhancement products for use on passenger cars, trucks and special interest vehicles of the type that could be affected by any regulation pertaining to chemical content of consumer products.

SEMA requests that the agency restore language that was included in a previous version of the draft regulation regarding "historic products." This language, which would exempt certain products from the scope of the regulation, appears below:

**69501. Purpose and Applicability**

*(4) This chapter does not apply to any historic product that is placed into the stream of commerce in California.*

**69501.2 Definitions**

*(41) "Historic product" means a product that is manufactured or produced prior to the date the product is listed as a Priority Product, and its service, replacement and repair parts produced after that date to repair as-built the historic product.*

It is essential that parts for automobiles remain available to California consumers to maintain vehicles and reduce emissions. Although we are very pleased that historic products and existing inventories of spare parts will be exempted from the regulation, we strongly believe that spare parts produced after that date to maintain and/or repair the historic product as-built should also be treated in this way.

Redesign of spare parts may be technically or economically infeasible due to declining production, economies of scale, consumer expectations and technical design that will render their redesign infeasible, or legally impossible, to ensure that the historic product as-built can meet safety, durability and emissions testing requirements. Without a historic product exemption, the cost of spare parts would be prohibitive and unacceptable to consumers resulting in vehicles being taken off the market due to non-availability of spare parts, as well as having adverse environmental and equal justice consequences.

SEMA members offer thousands of replacement parts to consumers many of which are reviewed, tested and approved in accordance with the Air Resources Board's Executive Order program. To go back and redesign and validate a post model part for the small volume service demand resulting from a material change would be cost prohibitive. The basic economic business model for spare parts is that manufacturers put a marginal supply of spare parts in stock during the production time of a running series. They do not produce spare parts for the total lifetime of the vehicle due to the high costs of warehousing. Thus, to the extent that customers need spare parts beyond what is initially stocked, there is a reproduction-on-demand market whereby suppliers use the "original" tools, materials, production processes and engineering specifications to continue to ensure that vehicles already purchased by consumers can continue to be maintained and in service, as consumers bring their cars in for repair.

If the current service parts supply market is no longer available due to a need to comply with these regulations, the spare parts will need to be redeveloped and sold at much higher costs. The development of a new spare part will involve development of alternative/substitute materials, design/engineering changes, new suppliers, new releases, new durability tests, new system Type Approval (TA), part number changes and far higher costs due to all these factors and declining volumes needed. It is not only impractical, but may be impossible in many instances. If the material formulation changes for a spare part after the end of production of the vehicle, then it will be necessary to ensure that we are delivering components that were tested to comply with federal safety or emissions standards. When production of a vehicle has ceased, such testing is unwarranted.

Again, redesigning motor vehicle parts would result in little benefit while the amount of effort involved makes it infeasible, impractical and in most cases impossible. California parts manufacturers and retailers can ill afford another burdensome regulatory requirement in an economy where sales and profit margins are already minimal.

Thank you for your consideration. We are available to answer any questions you may have.

Steve McDonald  
SEMA Vice President, Government Affairs

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**San Francisco Bay Regional Water Quality Control Board**

October 10, 2012

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

Subject: Proposed Safer Consumer Products Regulations  
(Dept. Reference No. R-2011-02, File No. Z-2012-0717-04)

Dear Ms. Von Burg:

On behalf of the State Water Resources Control Board (State Water Board) and the Regional Water Quality Control Boards (Regional Water Boards), we are submitting these comments on the Department's proposed Safer Consumer Products regulations. We generally support the most recent proposal and wholly support the overarching goals of the regulations, which aim to identify and prioritize chemicals of concern and promote safer alternatives.

The State Water Board and nine Regional Water Boards are responsible for maintaining water quality in State waters to protect beneficial uses of surface and ground waters. As a result of discharges of chemicals available through ordinary commerce, we have found many water bodies in the State to be impaired pursuant to Clean Water Act section 303(d). The Clean Water Act requires us to prepare resource-intensive plans to restore the beneficial uses of these waters, and programs to implement these plans are extremely expensive, both for us and for the regulated community. For many pollutants of concern, end-of-pipe treatment of wastewater and stormwater is not only prohibitively expensive, but technologically infeasible.

The proposed Safer Consumer Products regulations have great potential to reduce public and environmental exposure to harmful and unnecessary chemicals. As explained below, we believe the regulations could go further in addressing water quality concerns.

### **1. Clean Water Act Section 303(d)**

The "303(d) List" should be added to the Safer Consumer Products regulations. Federal Clean Water Act section 303(d) requires that the Water Boards assess water quality data for California's waters every two years to determine if they contain pollutants in excess of water quality standards. The resulting list is based on actual water quality data and sets forth California's highest water quality priorities. The list is consistent with the Chemical List Criteria of the Safer Consumer Products Initial Statement of Reason (pg. 60, Initial Statement of Reason).

**Recommendation:** Add the “303(d) List” to the regulations under section 69502.2(a), Chemicals of Concern Identification (pg. 21, line 21).

## 2. Emerging Concerns

In previous comments dated March 14, 2012, the State Water Board suggested adding the publicly reviewed Chemicals of Emerging Concern list generated by a scientific panel in accordance with the State Water Board’s Recycled Water Policy.<sup>1</sup> We reiterate that comment and further suggest adding the Chemicals of Emerging Concern list generated by a second scientific panel for freshwater, coastal, and marine ecosystems.<sup>2</sup> If not sufficiently controlled, chemicals of emerging concern may become major drivers of future water quality impairment. The Safer Consumer Products regulations should anticipate and prevent future water quality problems. These Chemicals of Emerging Concern lists are consistent with the Chemical List Criteria of the Safer Consumer Products Initial Statement of Reason (pg. 60, Initial Statement of Reason).

**Recommendation:** Add the Chemicals of Emerging Concern lists generated for the State Recycled Water Policy and for freshwater, coastal, and marine ecosystems to the regulations under section 69502.2(a), Chemicals of Concern Identification (pg. 21, line 21).

## 3. Alternatives Analysis Threshold Exemptions

We support the Department’s approach to the exemption in section 69503.5(c), Alternatives Analysis Threshold Exemption (pg. 31, line 29). The proposed threshold is based on a chemical concentration by weight to be specified for each priority product, and not a scientifically baseless one-size-fits-all percentage. Different pollutants and different products have different potencies. The case-by-case language allows for variations in product usage and environmental sensitivities.

## 4. Initial Priority Products

Please modify the regulations to better address non-human environmental pollution, including serious water quality concerns. As currently drafted, the proposed regulations postpone consideration of some of the highest priority water quality problems in the State (e.g., copper, nickel, phosphates, nitrates, selenium, boron). For the first few years, chemicals selected as initial priorities must meet both human health and environmental criteria. This approach excludes many water pollutants because, although they may pose significant water quality threats, they often pose few human health risks. Selecting one of the five initial priority products to address a purely water quality threat would better illustrate the applicability and benefits of these regulations.

As currently written, the proposed regulations identify two groups of Chemicals of Concern. The first group includes chemicals exhibiting one or more hazard traits (i.e., carcinogenicity, reproductive toxicity, mutagenicity, developmental toxicity, endocrine disruption, neurotoxicity, or bioaccumulative toxicity); the second group includes chemicals on exposure indicator lists for water quality, air quality, or biomonitoring. The 303(d) list and Contaminant of Emerging

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<sup>1</sup> [ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/CECpanel/CECMonitoringInCARecycledWater\\_FinalReport.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/CECpanel/CECMonitoringInCARecycledWater_FinalReport.pdf)

<sup>2</sup> [ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/692\\_CEEcosystemsPanelReport\\_Final.pdf](ftp://ftp.sccwrp.org/pub/download/DOCUMENTS/TechnicalReports/692_CEEcosystemsPanelReport_Final.pdf)

Concern lists could conceivably be added to either group, under section 69502.2(a)(1) or section 69502.2(a)(2), Chemicals of Concern Identification (pg. 21, line 24, and pg. 22, line 24), because the chemicals on these lists are generally toxic, bioaccumulative, or have otherwise demonstrated specific hazard traits in water. Several alternatives strategies exist for the Department to select an initial priority product based solely on its water quality implications.

**Recommendation:** Add the 303(d) list and the Chemicals of Emerging Concern lists generated for the State Water Board's Recycled Water Policy and for freshwater, coastal, and marine ecosystems to section 69502.2(a)(1), Chemicals of Concern Identification (pg. 21, line 24).

**Recommendation:** Alternatively, add these lists to section 69502.2(a)(2), Chemicals of Concern Identification (pg. 22, line 24), and modify section 69503.3(g), Process to Evaluate Products Using the Prioritization Factors (pg. 29, line 5) as shown below:

- (g) Initial Priority Products List(s). Prior to January 1, 2016, the Department may list a product as a Priority Product only if the product is being listed on the basis of one or more Chemical(s) of Concern in the product that meet ~~both~~ two of the following criteria:
- (1) The chemical meets one or more of the criteria specified in subsection (a)(1) of section 69502.2; ~~and~~
  - (2) The chemical meets one or more of the criteria specified in subsection (a)(2) of section 69502.2; ~~or~~
  - (3) The chemical is on the Clean Water Act §303(d) list of impaired water bodies or a Chemicals of Emerging Concern list generated for the State Water Board's Recycled Water Policy and for freshwater, coastal, and marine ecosystems.

## 5. Transparency and Public Involvement

Please strengthen opportunities for transparency and public involvement. We applaud your approach to balancing intellectual property rights with the need to identify chemical product exposure pathways. Lack of access to chemical data, coupled with few mechanisms to remove harmful chemicals from the marketplace, has led to health and environmental harm. Regulatory transparency, including opportunities for public involvement, will be crucial to the success of your program. Innovation thrives when information is clear and available.

Effective pollution problem-solving can be compromised when exposure pathways to surface waters are overlooked. Explicit identification of exposure pathways through a simple conceptual model early in the process, coupled with public participation, could help ensure that all exposure pathways are identified and none are omitted. As written, this information would not be available until the Final Alternative Analysis is completed and public opportunities to influence the process are more limited.

Similarly, public participation in the development of work plans and stewardship plans will ensure that the best ideas are considered and implemented. For example, the California

Department of Resources Recycling and Recovery is inviting public input on its carpet and paint product stewardship plans.

**Recommendation:** Require a simple conceptual model with the Preliminary Alternatives Assessments work plans under section 69505.3, Alternatives Analysis: First Stage (pg. 41, line 10).

**Recommendation:** Include a formal public comment period under section 69505.3, Alternatives Analysis: First Stage (pg. 41, line 10), and for any significant work plan revisions.

**Recommendation:** Invite input from State and local government agencies and the public prior to approving stewardship plans under section 69506.8(a)(2)(A), End-of-Life Management Requirements (pg. 58, line 1).

**Recommendation:** Include the following in section 69501.5, Availability of Information on the Department's Website (pg. 18, line 42):

- All documents related to the three recommendations above.
- All materials cited in section 69505.1(h), Alternative Analysis General Provisions (pg. 39, line 1), and related public comments and correspondence with interested parties.
- Proposed stewardship plans prepared pursuant to section 69506.8(a)(2)(A), End-of-Life Management Requirements (pg. 58, line 1), not only final plans.

## 6. Costs

Please expand the assessment of the economic impact of the proposed regulations. As written, the findings do not assess the financial impacts on communities exposed to unregulated chemicals. Ecological impacts are difficult to anticipate and their costs are difficult to estimate, but the costs are real and significant. When such expenses are borne by government agencies, they are often over-looked. In 2001, U.S. EPA estimated that the average cost to develop solutions for any of the roughly 20,000 impaired water bodies was about \$52,000 (the range was \$26,000 to \$500,000).<sup>3</sup> These figures do not include implementing the solutions, which is far costlier, and costs are rising. The future costs of addressing emerging contaminants could be greater still. Prevention efforts, such as those outlined in the proposed regulations, will be far more cost effective. However, to demonstrate this, the full costs of environmental cleanup efforts must be considered.

**Recommendation:** Consider more deeply the costs associated with mitigating water pollution impacts after they occur under section 69505.4(a)(2)(C), Alternatives Analysis: Second Stage, Economic Impacts (pg. 43, line 28).

**Recommendation:** Address water pollution control costs not only in the Alternative Analysis but also in regulatory decision-making. Add language to section 69503.2, Priority Products Prioritization Factors (pg. 25, line 20), and section 69506(c), Regulatory Response Selection

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<sup>3</sup> <http://water.epa.gov/lawsregs/lawsguidance/cwa/tmdl/costfact.cfm>

Principles (p.52, line 15), to consider the costs sustained by government agencies, publicly owned treatment works, non-profit organizations, and private businesses that handle wastes and oversee environmental clean-up efforts.

## 7. Schedule

To make the most of the new regulations, regulatory timeframes should be as short as possible. As written, there is no timeline for the regulatory response process and too much flexibility to extend the process. We hope the Department can avoid drawn-out phase-outs of chemicals contributing to health and environmental harm. The regulations should include specific findings to justify any flexibility provided to extend a schedule.

***Recommendation:*** Make timely action a priority by including a timeline in section 69506, Regulatory Response Selection Principles (pg.52, line 6).

Thank you for this opportunity to offer our input regarding the Safer Consumer Products regulations, and for your hard work and persistence in drafting these regulations. They represent a critical step in chemical policy reform. Because the regulations represent the first comprehensive state effort to find and require safer alternatives, they will likely become a national model. We appreciate your responsiveness to our concerns, and we are confident that the Safer Consumer Products regulations will greatly benefit water quality throughout the State. If you have any questions, please contact Dylan Garner at (510) 622-2116 or by e-mail at [dgarner@waterboards.ca.gov](mailto:dgarner@waterboards.ca.gov).

Sincerely,

Thomas Mumley  
Assistant Executive Officer



October 11, 2012

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

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

Subject: Safer Consumer Products Proposed Regulation

Dear Ms. Von Burg:

Stoner Incorporated appreciated the opportunity to meet with the DTSC staff twice on this proposed regulation. For over 70 years, Stoner has been committed to manufacturing and marketing safe and effective products to our customers. We operate two facilities in Lancaster County, Pennsylvania. Stoner Inc. was a 2003 recipient of the Malcolm Baldrige National Quality Award and is committed to continually improving our manufacturing processes and our products to better serve the consumer. Included in these improvements are the protection of human health and the environment. Some of our many, useful products are found in retail stores such as Wal-Mart, Target, and AutoZone. Stoner pursues a mission of helping our customers save time, increase their productivity, and improve the quality of their work.

Stoner Inc. is pleased that the DTSC is focusing on up to Five Priority Products for their initial review. However, without DTSC identifying these products, commenting on the proposed regulation is difficult.

Our primary concerns are the following:

**Chemicals of Concern (COC).**

DTSC should provide a comprehensive list of chemicals of concern, not a list of lists. Stating lists is cumbersome and leads to confusion. Numerous chemicals would be listed two, three, four, and even more times. Providing lists also leaves the opportunity for chemicals to be added or deleted. For this regulation a known set of chemicals should be identified in detail. In addition, the number of COC listed on the lists is unmanageable. The number of COC should be significantly reduced.

**Alternative Analysis Threshold.**

DTSC needs to clearly articulate a number for this threshold. Providing a chemical-by-chemical Alternative Analysis Threshold is not workable. A known scientific de minimus exemption should be granted. Leaving the threshold number to be determined for each chemical will be extremely time consuming. In addition,



threshold numbers set at extremely low levels will be difficult to monitor and financially burdensome for small companies such as ours.

**Qualifications for Assessors**

The requirements for Alternative Assessment (AA) Assessors are substantial. Small to medium size companies need to be able to use their in-house technical staff. As a Ph.D. Chemist for Stoner Inc., my experience and overall knowledge of Stoner Inc.'s products make me the best entity to perform the AA on these products. The current requirements and timelines would be extremely difficult for a small company such as ours to meet. These requirements should provide companies such as ours with alternative requirements to utilize current staff.

**Confidential Business Information**

Formulas for small companies such as Stoner Inc. are the life-blood of the company. The formulas need to be guarded from competitors since it is this confidential business information that allows us to remain in business. The regulation does not provide for this protection. Thus, the regulation needs to guarantee that such data will be kept confidential.

In summary our major concerns are lack of clear description of chemicals of concern, lack of a harmonized de minimus threshold, excessive requirements for Alternative Assessment Assessors and inadequate protection of confidential business information.

Stoner appreciates your consideration for our concerns. Feel free to contact me at

Sincerely,



Robert W. Sweger, Ph.D.

- CC: Odette Madriago, DTSC
- Debbie Raphael, DTSC
- Gareth Elliott, Office of the Governor
- Matthew Rodriguez, California Environmental Protection Agency
- Kristin Stauffacher, California Environmental Protection Agency
- Laurie Nelson, Randlett/Nelson/Madden
- Doug Raymond, Raymond Regulatory Resources (3R), LLC
- Harry Zechman, Stoner Incorporated

## GCREgs@DTSC

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**From:** TSIA-Celia Shih <celia@itri.org.tw>  
**Sent:** Thursday, October 11, 2012 2:22 AM  
**To:** GCREgs@DTSC  
**Cc:** Madriago, Odette@DTSC; Wong, Jeff@DTSC; tywu@tsia.org.tw; fmhsua@tsmc.com; H\_R\_Lai@umc.com; joey@ITRI.ORG.TW  
**Subject:** TSIA comments on proposed SCP regulations, California Regulatory Notice Register (Z-2012-0717-04) published on July 27, 2012  
**Attachments:** draft ICT industry comments on proposed SCP regulations\_oct 10.pdf  
**Importance:** High

Dear Ms. Von Burg:

On behalf of the Taiwan Semiconductor Industry Association (TSIA), we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxic Substances Control (DTSC), published in the California Regulatory Notice Register (file number Z-2012-0717-04) on July 27, 2012.

TSIA is the trade association of the semiconductor industry in Taiwan. More information about our organization can be found at <http://www.tsia.org.tw>

We are writing in support of the comments filed on October 11, 2012 by several technology associations based in the United States. The organizations are the Information Technology Industry Council (ITIC), TechAmerica, the Consumer Electronics Association (CEA), and the Semiconductor Industry Association (SIA) in the United States. The members of TSIA have reviewed the comments of these other technology associations and we endorse these comments. As discussed in detail in those comments, we believe that these proposed regulations set forth a burdensome and subjective regulatory scheme that will be infeasible and expensive for manufactured products such as semiconductors. In addition, we believe that some requirements may represent a technical barrier to trade (TBT) under the rules of the World Trade Organization (WTO), and could result in the disclosure of trade secrets and confidential business information (CBI).

We appreciate the opportunity to provide input on these proposed regulations.

Sincerely,

TY Wu, President

FM Hsu, ESH Committee Chair

Taiwan Semiconductor Industry Association  
Rm1246, Bldg 51, 195, Sec. 4 Chung Hsing Rd., Chutung, Hsinchu, 310 Taiwan ROC  
URL: <http://www.tsia.org.tw>

contact: Ms. Celia Shih  
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Electronics Industry Comments on Proposed Regulation on  
Safer Consumer Products  
(July 2012)

ITI, TechAmerica, the Consumer Electronics Association (CEA) and the Semiconductor Industry Association (SIA), are pleased to provide these comments on behalf of the information technology, consumer electronics, and semiconductor industries on the Proposed Regulation for Safer Consumer Products (Proposed Regulation). We appreciate the opportunity to provide input on the Proposed Regulation and we look forward to working with the California Department of Toxic Substances Control (DTSC) as the Regulation is finalized and implemented.

Our member companies have long been leaders in innovation and sustainability, often taking measures to exceed regulatory requirements on environmental design, energy efficiency and product stewardship. ITI, TechAmerica, CEA and SIA are submitting these comments in order to promote the development of consumer product regulations that will expand on the environmental efforts of our member companies and drive improvements in environmental performance and ensure California's continued leadership in technological innovation.

**General Comments:**

We offer specific comments on sections of the Proposed Regulation below, but wish to offer several overarching comments. As we have mentioned in our previous comments, when AB 1879 was signed into law by then Governor Schwarzenegger, Governor Schwarzenegger specifically noted that AB 1879 and its implementing regulation were to draw on "lessons learned" in other jurisdictions, and take into account programs in other states, countries and regions, such as the European Union, and build upon their experience, data and expertise.

Unfortunately, it does not appear that the Proposed Regulation was developed with the perspective of learning from other jurisdictions' experience in developing chemical regulations. In previous comments, we have provided several examples of how such experience and expertise can be used to improve the Proposed Regulation; however, we have seen little improvement in this area. We suggest that the DTSC consider how other jurisdictions regulate chemicals used in consumer products when redrafting these regulations.

Overall, the electronics industry considers the Proposed Regulation to be an improvement over the informal draft regulations that were released in 2011, but we still have significant concerns with the Proposed Regulation. The Proposed Regulation presents a very onerous and potentially costly regulatory scheme that is predicated on significant paperwork requirements, for both industry and the DTSC, and an overreliance on testing that, especially for manufactured products (e.g., articles), will be difficult and expensive, while providing few, if any, environmental benefits.

The electronics industry is concerned that the Proposed Regulation is overly subjective and needs to be more focused on objective and standardized processes. It is critical that any person doing a regulatory analysis or determination under these regulations will be able to reach a similar conclusion. Currently, the Proposed Regulation is overly deferential to the DTSC and too discretionary in several areas, mostly but not exclusively in the prioritization and regulatory response areas, for which we've provided specific comments.

While we appreciate that the DTSC is looking for flexibility to allow for changes in science and in response to new information in chemicals management, in many cases, the overly-flexible language only provides ambiguity, does little to provide the regulated community with regulatory certainty, and could provide a disincentive to voluntary actions in the marketplace. While the DTSC has recently assured industry that the regulatory assessment process will be consistent across individual cases, future administrations may take different approaches if given the regulatory authority to do so. We suggest that, in particular, the DTSC provide clear processes for prioritization and clear triggers for regulatory actions. There should also be a provision allowing for the regulations to be revisited if there are changes in the scientific or economic landscape.

The electronics industry suggests removing the term “homogenous material” from the Draft Regulations, but retaining the concept and intent of targeting specific materials within a larger consumer product by modifying the definitions of “component” and “consumer product.” While we agree with the intent of regulating specific uses of a material in certain and clearly defined cases, the term “homogenous material” has been problematic, even the improved version that is contained in the European Union’s revised RoHS Directive (termed “RoHS Recast”)<sup>1</sup>. In our comments, we suggest that, by modifying the definitions of “component” and “consumer product,” the DTSC will have the ability to target chemicals of concern in specific materials, but will not propagate a still problematic definition contained in another regulatory program.

We believe that several provisions contained in the Proposed Regulation, especially those requiring testing, may constitute a technical barrier to trade) under the World Trade Organization’s Agreement on Technical Barriers to Trade<sup>2</sup>. When suggesting restrictions on the use of any chemicals, the DTSC must be able to list acceptable, internationally-recognized testing methods that will allow manufacturers to demonstrate compliance with the regulatory requirements. However, testing should not be viewed as the only means of demonstrating compliance as there are often less costly and destructive means to determine regulatory compliance, such as supply chain disclosures and material declarations.

The electronics industry continues to oppose the use of Certified Assessors in Article 8. We provide more detailed comments on this Article below, but we believe that the use of Certified Assessors will not provide any certainty to the DTSC, public or manufacturers that the assessment has been done correctly and thoroughly, and can, in fact, raise significant legal issues for the Assessors, the manufacturers and the DTSC. The use of a Certified Assessor, with DTSC review and acceptance of the

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<sup>1</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF>

<sup>2</sup> <http://www.worldtradelaw.net/uragreements/tbtatreement.pdf>

Alternatives Assessment (AA) results, raises a basic question up for debate as to who is ultimately responsible, and subsequently liable, for the selection of materials in a product. We have stated repeatedly in previous comments that an AA is only one data point of several that inform the decision of which materials are selected for use in a product. We believe that the DTSC is erroneous in assuming that there will be a clear “winner” material in an AA that should be used above all others. It is rarely the case that an assessment will provide an overwhelmingly clear answer.

Finally, the Proposed Regulation raises several concerns related to trade secret and confidential business information (CBI) protections. In several parts of the Proposed Regulation, requirements are established that would require manufacturers to supply information to the DTSC, such as specific information related to sales and manufacturing processes, which are often closely-held, private business information. ITI, TechAmerica, CEA and SIA recommend that the DTSC review the information that is being requested and consider the potential trade and business ramifications of divulging such information. We make specific comments on this important issue in our review of specific sections of the Proposed Regulation below.

### **Specific Comments by Section:**

#### **Article 1. General**

##### **Section 69501.2 Definitions**

“Homogenous Material” – Because of the difficulty with the term “homogenous material” we suggest removing this definition (part 34) from the regulations in its entirety. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but as mentioned previously, the definition of “homogenous material” is not viewed as well defined in the EU RoHS Directive by all stakeholders, and attempting to harmonize with a term that is problematic to some in the industry will make compliance difficult for both the Department and manufacturers.

Additionally, while we support the continued exclusion of “Historic products” from the definition of “Consumer product” and therefore from being subject to these regulations, we note that the proposed definition fails to include any necessary repair or replacement parts to maintain such products. The continued manufacture and availability of repair and replacement parts without being subject to these regulations is critical to maintaining the cost-effective support and operation of these products for our customers. As noted in the Initial Statement of Reasons (ISOR), the definition of “manufacture” (40) is intended to also exclude “replacement parts” as may be required to repair or refurbish an existing consumer product, although the actual proposed definition fails to reference replacement parts. We recommend below that these definitions be modified accordingly.

Thus, we recommend that the definitions of “Component” and “Consumer Product” be changed to read:

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

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

(C) Is intended to be included as a part of a finished item

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

1. A “consumer product,” including component, as defined in Health and Safety Code section 25251, that is identified under section 69503.4(a)(2)(B), as the minimum required focus of an AA.

(B)1. “Consumer product” or “Product” does not mean any historic product.

2. “Historic product” means a product that ceased to be manufactured prior to the date the product is listed as a Priority Product, and includes its service, replacement and repair parts regardless of when manufactured that are necessary to maintain and/or repair the historic product.

(C) “Consumer product” or “Product” does not mean a product previously owned or leased by someone other than the manufacturer, importer, distributor, or retailer of the product.

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

(A) Repair or refurbishment of an existing consumer product, including the manufacture of repair or replacement parts;

(B) Installation of standardized components to an existing consumer product; or

(C) Making non-material alterations to an existing consumer product.

Additional definitional recommendations:

**(26) “End-of-life”** – This definition would encompass stages of a product life cycle where products may be reused or refurbished and, therefore, are not considered to be at their “end-of-life.” This is an important distinction for electronic products. We suggest tying the end-of-life to when a product enters the waste stream and no longer has useful life.

We believe that DTSC could address this concern by changing the definition of (26) to read:

(26) “End-of-life” means the point when the product is at the end of its useful life, and is discarded for recycling or disposal by the consumer.

**(52) “Reliable information”** – We are concerned that the definition of “reliable information” assumes that too much information is *de facto* deemed “reliable” simply because it has been published in peer reviewed journals or by state regulators. We believe neither of these scenarios automatically make information “reliable” We recommend that, due to the limitations of peer review<sup>3</sup> and state agency reports, that a process for disputing the reliability of such information be included. .

Recommendation:

We suggest revising the definition of “Reliable information” to read as follows:

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<sup>3</sup> See OMB’s Information Quality Guidelines, 67 Fed. Reg. 8452, 8455 (Feb. 22, 2002).

(52) (A) “Reliable information” means a scientific study or other information that is one or more of the following:

1. Published in a scientifically peer reviewed report or other literature;
2. Published in a report of the United States National Academies;
3. Published in a report by an international, federal, state, or local agency that implements laws governing chemicals; and/or
4. Conducted, developed, submitted, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes.

(B) Interested parties may dispute the information from the Department in public workshops or during comment periods.

## **Section 69501.2. Duty to Comply and Consequences of Non-Compliance**

(a) Duty to Comply.

Subpart (a)(2) should allow a consortium, trade association, public-private partnership, or other to apply for technology-specific exemptions under sections 69503.6 and 69503.7, rather than each company being required to do so independently. Thus, to minimize the compliance burden on individual companies, we recommend the following:

Change subpart (a)(2) to read:

The requirements of this chapter applicable to a responsible entity may be fulfilled by a consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity.

(b) Manufacturer and Importer Options.

(b)(1) and (2) - These notification requirements will only serve to burden manufacturers and the Department, with no discernible benefit to the environment, and (b)(2) will significantly increase the burden of placing new products on the market. The Department has consistently stated that the regulations must reward innovation. However, these requirements will significantly slow the introduction of new products in the California market.

We believe one way that DTSC could address this concern is as follows:

Change subpart (b) (1) and (2) to read:

if a priority product is either removed from commerce in California, or if the product has been redesigned to remove or reduce the chemical(s) that were the basis of an AA or replaced, the manufacturer must be able to demonstrate to the Department’s satisfaction, upon request, that the product has been removed from commerce or redesigned or replaced in the marketplace.

A similarly simplified process should also be applied to the Retailer Option under subpart (c).

#### **Section 69501.4. Chemical and Product Information**

The Department should not request information from responsible parties unless publically-available sources of information have been exhausted. We suggest that the Department specify that the approaches outlined are in order of preference.

It is not clear how the Department will handle cases where responsible parties do not have the information being requested or if there is conflicting information between sources of information; in particular for information submitted by responsible parties.

#### **Article 2. Chemicals of Concern Identification Process**

##### **Section 69502.2. Chemicals of Concern Identification**

While we appreciate that the lists presented in the regulation have been pared down from previous versions, the list of chemicals identified by the list of lists in § 69502.1 will still be in excess of 1,000 chemicals. We are concerned that the purpose of this list will be misconstrued by companies in the supply chain as well as by governments, NGOs, and in particular by members of the general public whose lack of understanding with this complex regulation may lead to unfounded fear. It is very likely that the chemicals identified by this process will have a stigma attached to them that will cause their use to be unnecessarily challenged or questioned, even though the chemicals may have already undergone an assessment or have been determined to be safe in specific applications. The electronics industry believes that the approach suggested by Mr. Mike Rossi of the Governor’s office is appropriate for the chemicals of concern identification process, which is reflected in our recommendation below.

Further, we believe that there should be different terms to address specific instances in the regulation. The term “Chemical of Concern” (CoC) currently means a chemical on the list per section 69502.2 that exhibits a hazard trait; the chemical paired with a specific product and the focus of the alternatives assessment in sections 69503.4 and 69503.5; and could mean any chemical requiring reporting to the Department in section 69505.5 or disclosure in consumer information in section 69506.4. Using different terms in different instances will clarify what the Department is referring to at any part in the regulatory process.

Recommendation:

The electronics industry recommends a two-part process for identifying chemicals of concern. First, a list of “Chemicals of Interest” are developed using the process in Section 69502.2, then a pared-down “Chemicals of Concern” list is developed from the “Chemicals of Interest list” and specific factors identified by the Department. Finally, a “Priority Chemical” is a chemical that has been pared with a priority product and is the focus of the Alternative Analysis. This Priority Chemical will also be the focus of any regulatory actions that stem from the AA.

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

### **Section 69503.1. Applicability**

The Statement of Reasons document for these regulations is very clear that products that do not contain a chemical of concern are not subject to the requirements of this section. However, the regulations are not as clear on this point.

Recommendation:

There are two options that we believe address this concern.

Option 1 - Add a second sentence:

This section is not applicable to products that do not contain one or more chemicals of concern.

Option 2 – Modify the definition of Priority Product:

(48) “Priority Product” means a product containing one or more Chemical(s) of Concern as identified and listed as a Priority Product by the Department under section 69503.4.

### **Section 69503.2. Priority Products Prioritization Factors**

The regulations have several factors that include the concept of exposure, but exposure of a chemical of concern is not a factor in the prioritization. While the regulations do contain subpart (a)(1)(B), the regulations seem to assume that any exposure to a product equates to exposure to the chemical of concern, so this subpart relates to exposure to the product, not to the chemical of concern.

“Containment of the Chemical” within the product is included in the product prioritization criteria in subpart (a)(1)(B). As described in the ISOR, “how the Chemical of Concern is contained or bound during the use of the product determines, in part, the amount of exposure that may occur. For instance, the Chemical of Concern may be a component inside a product and may not be accessible to the user, in which case, there is little to no exposure as a result of use of the product.” These are meaningful and practical ways to assess exposure to a chemical in a complex product or article and should be retained. We suggest that the Department add language in subpart (a)(1)(B) to clarify that “containment” includes the concept of accessibility as described in the ISOR. “Accessibility” is a commonly-accepted term with well-established tests for whether a part of a product is accessible or not for chemical exposure purposes, such as the test used by the Federal Consumer Product Safety Commission.<sup>4</sup>

Finally, subpart (a)(1)(B)(4)(a) discusses chemical exposures during manufacturing. The Department has been consistent in stating that these regulations cover consumer products and chemicals. Exposures during manufacturing processes are already covered under existing authority by the federal Occupational Safety and Health Act (OSHA), and should not be included in these regulations.

Recommendation:

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<sup>4</sup> <http://www.cpsc.gov/about/cpsia/inaccessiblefr.pdf>

We recommend that this section, in particular subpart (a)(1)(A), be greatly simplified and specifically mention exposure as a factor. One way that DTSC could address this concern is as follows:

Change (a)(1) to read:

Adverse impacts and exposure. The Department will consider the adverse public health and environmental impacts posed by the Chemical(s) of Concern in a product due to the physicochemical properties, environmental fate, hazard traits and the possibility and likelihood of exposure to the Chemical(s) of Concern through reasonably foreseeable use and abuse of the product.

Additionally, we believe further clarity could be provided by the following:

Change (a)(1)(B)(4)(d) to read:

Containment of the Chemical(s) of Concern within the product, which includes whether the Chemical(s) of Concern is in an inaccessible component within a product.

Subpart (a)(3) also has the Department “considering” other California and federal laws. The electronics industry strongly believes that, as in previous drafts of the regulations, devices that are already regulated for a particular chemical use must be exempt from these regulations. The potential for multiple, conflicting and confusing regulatory schemes is too great to simply make those a factor for consideration. At the least, there should be considerations for exempting products that are previously regulated under other international or federal chemical regulatory regimes. There should be a presumption that chemical risks have already been reduced in such cases.

Subpart (b) lists key prioritization factors the Department will consider. We believe this process is more complicated than in previous drafts, and suggest the Department consider expanding these key criteria to make it clearer when a product may meet them.

Recommendations:

We suggest the Department give priority to products meeting the following criteria:

- (1) The chemical of concern in the product have a significant potential to cause adverse public health or environmental impacts;
- (2) The product is widely distributed in commerce and widely used by consumers;
- (3) There is significant potential for public and environmental exposures to the chemical(s) of concern in the product in quantities that can result in adverse public health or environmental impacts; and
- (4) For assembled products, the product contains one or more chemicals of concern that may present potential exposure(s) through inhalation or dermal contact in quantities that can result in adverse public health or environmental impacts during intended and reasonably foreseeable use.

### **Section 69503.3. Process to Evaluate Products Using the Prioritization Factors**

While this section is labeled a process, the electronics industry does not believe this is truly a process as required by AB 1879. As we mention in our general comments on the regulations, we are concerned that any person, or any administration, conducting this process will not generate similar results. While we appreciate that different entities (i.e., manufacturers vs. regulators) will have different assumptions and potentially different expertise, the process should still be sufficiently standardized so that anyone who does the process in good faith will come up with a similar result. We are not convinced that this is the case with the SCP regulations. There is simply too much discretion and variation in the steps enumerated in this section.

We recommend that the DTSC revert to the flow chart process that the DTSC used previously. A flow chart approach or, at least, a step-wise approach will be more systematic and less subjective than the current proposal.

Subpart (f)(1)(B) allows the Governor's office to potentially skip all of the Article 2 Chemical of Concern identification, and to unilaterally give priority to a chemical without any process or public input. While the final list would be open for public comment, it would be too late in the process to respond to any potential issues stemming from a Governor's Executive Order. We believe this is too broad a mandate and needs to be either removed or moved to the CoC identification in 69502.2.

### **Section 69503.4. Priority Products List**

Subpart (a)(2)(B) introduces the concept of the highly durable product. While we appreciate the intent of this term, we are not sure that it will adequately distinguish between formulated products and articles, and we believe that the limits placed on the department for selection of components and materials (10 per product every 3 years) are not useful. Alternatives assessments on articles are often very long and complex undertakings. For example, the US EPA Design for Environment program has been investigating alternatives for decaBDE in plastic casings. This assessment has taken over 3 years and has consumed several hundred thousand dollars, and has just gone out for public comment. While we recognize that this case is more complex than many others, it is still not unusual for assessments on electronic products to take two – three years. Having a limit of 10 things every three years will still potentially have manufacturers in a constant loop of mandated assessments.

Subpart (d) notes that the Department may respond to some or all public comments. We believe that for a truly credible process, the Department has the obligation to respond to all public comments. We do recognize that the response will be, in some cases, that a comment is without merit.

Recommendations:

(a)(2)(B) – Per our comments on homogenous material in Section 69501.1, we recommend changing (B) to read:

(B)1. If applicable, the component(s) and/or uniquely identifiable material(s) within a component, to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA.

2. For each Priority Product that is a highly durable product, the Department shall in all cases specify the number of component(s) and/or uniquely identifiable material(s) within a component to which the alternatives analysis threshold applies, and which is/are the required minimum focus of the AA. For each listed highly durable product, the Department shall specify no more than ten (10) components and/or uniquely identifiable materials per product every three (3) years.

### **Section 69503.5. Alternatives Analysis Threshold Exemption**

As mentioned in comments to previous Draft Regulations, we believe that the inclusion of cumulative concentrations (in subpart (d)) will add ambiguity to the regulations that will make it very difficult for the Department and manufacturers to determine compliance with these regulations. For example, if a chemical gets reclassified or a new chemical of concern gets added to an existing priority product, then industry and DTSC personnel will have to re-calculate all the existing threshold level summations as the grouping of chemicals subject to the threshold will change. Further, manufacturers will not be able to use existing data and compliance systems, which are all based on single chemical thresholds, to ensure compliance with these regulations. This will delay DTSC's ability to quickly and efficiently implement the new regulation as both industry and the agency will be required to develop innovative new business processes and/or software tools that are capable of calculating the summation of chemicals vs. applying the threshold to a single chemical. This will divert valuable agency resources to focus on documenting that chemicals are not present in products from the primary purpose of the regulation which is to identify safer consumer products.

Finally, it is not always possible to analytically quantify all chemicals in a consumer product, especially for assembled products which may have matrix interferences, or some inorganic compounds with only analytical methods for the elements but not the full chemical compound. Therefore, having the threshold potentially set at a cumulative sum of chemicals and not an individual chemical increases the complexity of quantification to a sum total as more and more chemicals may fall into the category of "unquantifiable." As the department adds more chemicals to a priority product, the cumulative sum threshold will become more and more difficult to quantify as the thresholds get smaller and smaller going below any ability of analytical detection limits. This uncertainty will be exacerbated in more complex assembled products and will only make the compliance demonstration and/or enforcement more difficult.

The electronics industry acknowledges the importance of considering cumulative chemical effects, however, we believe this should be considered during the product prioritization phase and can be addressed through regulatory responses, but it is not appropriate for a threshold determination.

### **Section 69503.6. Alternatives Analysis Threshold Exemption Notifications**

The electronics industry continues to believe that these minimum threshold exemptions should be self-implementing. The amount of information being requested by the Department to demonstrate that the levels are below that which should be regulated will be overwhelming to the regulated community and the Department. Additionally, there is a dependence on testing results to “prove the negative” that a chemical is not in a product, where a compliance assurance system, which may include but does not require testing results, is in most cases much more practical for manufacturers to manage the content of their products and the Department to ensure compliance with the regulations.

Recommendations:

The electronics industry suggests that much of § 69503.6 be deleted, and replace with a compliance assurance process where the Department may request information from the manufacturer.

In creating a program to ensure compliance with the threshold exemption, the Department should remove the implication at § 69503.6(a)(5) and (a)(7) that only analytical testing results are appropriate substantiation that a product meets the threshold exemption. Given the sheer number of chemicals of concern based on regulations and customer restricted/banned substances lists, testing for all of these chemicals is cost-prohibitive. Therefore, manufacturers commonly rely on supplier certifications regarding purchased material content to understand product ingredients and impurities, and cannot routinely test all purchased materials or finished goods. Responsible manufacturers augment supplier information with testing when knowledge of the chemistry of the product indicates probable presence of chemicals of interest, or when there is cause to doubt the veracity of the supplier certification. This method has been widely used to determine compliance with international chemical restriction laws and regulations and is sufficiently rigorous and credible to provide a model for the Safer Consumer Products Regulation.

### **Section 69503.7. Priority Product Notifications**

As written, this section will inundate the Department with information as soon as a Priority Product list is published. The Department should reconsider the reporting and notification requirements in the regulations, considering the burden on the manufactures to produce this information and the Department to receive process and respond to it. It is not clear why the Department would need all of the information requested, in particular all of the information in subpart (a)(2).

## **Article 4. Petition Process for Identification and Prioritization of Chemicals and Products**

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

We are concerned that the requirement of subpart (b), that a chemical be off all lists, is an overly high hurdle to clear to request a petition. The lists in section 69502.2(a) are all updated on different cycles, with some taking significantly longer than others to refresh. If there is significant new information, it is unlikely that it will change all of the lists within a reasonable time frame. The section should allow petitioners to remove Chemicals of Concern on a showing of “preponderance of the evidence” that the scientific evidence supports removal.

Recommendation:

We believe one way that DTSC could address this concern is as follows:

(b) Change to read:

A person may not petition the Department to delist any chemical identified as a Chemical of Concern unless that chemical has been removed from at least one list identified in section 69502.2(a).

#### **Section 69504.1. Merits Review of Petitions**

This section contains a list of factors the Department will consider in making a determination of whether a petition will be denied or granted. However, the criteria listed are only applicable to petitions to add substances to the Chemical of Concern list. There should be factors for how a chemical may be petitioned for removal from the CoC list.

Further, we are concerned with the subjectivity of this section. As with previous sections, there should be assurances that the petitions will be reviewed with a process that is dependent only on the science and merits of the review. We suggest that the Department develop a process or explanation of how the factors will be applied so that petitions may be reviewed more consistently based on an objective determination.

#### **Article 5. Alternatives Analysis**

##### **Section 69505. Guidance Materials**

The electronics industry contends that not all methodologies to perform an assessment are of equal caliber. Therefore, we are concerned that a process that has less rigor than necessary may be promoted and accepted as guidance by the department, and processes that are applicable to one type of products but not others may be used by assessors that do not understand the products and how they are produced. Therefore, we suggest that the Department allow for public input into the guidance materials when they are posted.

##### **Section 69505.1. Alternatives Assessments: General Provisions**

As mentioned in our general comments, the electronics industry feels that several of the timelines presented in the Proposed Regulations are too short to be workable. We believe that subpart (b)(3)(C)

is an example of this. Some of our associations' member companies have done assessments using the guidance in previous drafts of the regulations, and the preliminary steps took longer than 180 days. For simpler products, it is possible that a shorter timeframe is practical, but for high tech products with a complex supply chain, 180 days is too little. We suggest allowing the Department to set due dates when the Priority Products List is published. Allowing flexibility for the due dates may provide manufacturers with the opportunity to work with their supply chain and develop meaningful AAs.

As we mention in our comments to Article 8, we believe the requirements for a Certified Assessor in subpart (e) should be removed. Notwithstanding our objection to the use of Certified Assessors, we further believe that the 2 year implementation is unworkable. If the department proceeds with a Certified Assessor program, the timeframe of 2 years from the effective date of the regulations is unworkable. For the first set of priority products, a manufacturer will start the AA before 2 years is over, but may not have been able to complete it. These manufacturers should not have to switch assessors mid-stream. The DTSC should instead allow that the AA's for the first round of priority products do not require a Certified Assessor.

Subpart (g) requires that manufacturers who reformulate their products submit significant information to show that the chemical of concern is no longer in the product. We believe that this is another example of an overly-burdensome and large information request that manufacturers will be required to prepare and the DTSC will be required to process with little or no benefit to the environment. We believe that as with the AA threshold, if the manufacturer reformulates the product, no further reporting should be due. If the DTSC does feel some notice is necessary, a simple notification with the contact information and a statement that the product no longer contains a chemical of concern should be adequate. As we have mentioned previously, it is impossible to "prove the negative" that a chemical is not present, and the regulations are overly reliant on product testing to demonstrate compliance. There are many examples of other reliable and credible ways to demonstrate conformance, including supply chain declarations and internal process controls. If the DTSC is going to require testing to demonstrate compliance, it is incumbent on the Department to specify which tests are acceptable to show compliance.

## **Section 69505.2. Analysis of Priority Products and Alternatives**

Subpart (b) notes that a responsible entity may submit an abridged AA report if an acceptable alternative is not "available or feasible." However, the Department does not specify thresholds for these terms. The Department should provide some guidance for feasibility in this section or in section 69505.3. Additionally, subpart (b) indicates that a responsible entity cannot do an Abridged AA Report without first doing a full Stage 1 study. We believe that a responsible entity should be able do an Abridged AA Report without first going through the process of a full Stage 1 study if they rely on information from other regulatory entities or trusted bodies to show that there are no viable alternatives.

Additionally, it is not clear how the Department will approve research and development (R&D) plans under this part and section 69505.3. It is unlikely that the Department will have the industry-specific expertise necessary to adequately review and approve R&D plans.

Subpart (d) allows for a responsible entity (manufacturer) to select a different alternative from the one identified in the Final AA Report. As we note in our general comments, this may raise the question of who is responsible for the material content of a product. It is not clear who will be ultimately responsible for a product material content if a manufacturer disagrees with the Certified Assessor. This subpart allows the manufacturer to assume that responsibility, but it is not clear why they may want to do this if a Certified Assessor has already made a recommendation.

Additionally, subpart (d)(1)(B) notes that the revised Final AA Report must be submitted to the Department 60 days prior to placing the product in the stream of commerce. What is the responsibility of the manufacturer if the proposed selected alternative is already in the stream of commerce?

### **Section 69505.3. Alternatives Analysis: First Stage**

Subpart (a) is an example of our comments in Section 69502.2, where different terms are needed to identify chemicals at different parts in the process. Using the same term depending on when referenced in the regulations is confusing. We recommend developing separate terms for these concepts in the regulation.

Subpart (b)(1)(A) notes the responsible entity must identify all legal requirements associated with the use of the product. However, the manufacturer is not likely to have this information. The manufacturers will have all compliance information for the manufacture of the product. We believe that this is what the DTSC is asking for in this section, but it should be made clear.

Subpart (b)(2)(A)1 states that alternatives must “eliminate or reduce the concentration” of the chemicals of concern in the product, but does not provide any threshold for this. As written, a trivial reduction of the CoC in the product through any means would meet this requirement. We suggest using the term “reduction in use” of the chemical of concern which will remove much of the ambiguity with the term.

The electronics industry is concerned with the requirement in (b)(2)(A)2 that a manufacturer shall consider alternatives posted for consideration by the Department. It is possible that a manufacturer has already considered these alternatives and should not be subject to doing so again, or based on the technical expertise of the manufacturer, they may be able to reject an alternative without the need for a full assessment. We suggest that the Department should not suggest alternatives, allowing the manufacturer to perform the AA, however, the Department could require the manufacturer to review and potentially explain why an alternative presented by the Department is not viable, but to require them to consider these in their AA is overly prescriptive.

### **Section 69505.4. Alternatives Analysis Second Stage**

In subpart (a)(2), the Department assigns all responsibility for collecting and using available information and tools on the responsible entity; however, as we have pointed out, a third-party Certified Assessor may actually be the entity performing the assessment, and the Department has reserved the right to agree or disagree with the assessment results. As we have mentioned several times, this can potentially pose a significant conflict, and it is not clear who is ultimately responsible for the results of the AA. It is possible that the Department or Certified Assessor may second guess the manufacturer (responsible entity) and it is not clear what recourse, if any, the manufacturer has in these cases.

The electronics industry is concerned that the economic impacts in subpart (a)(2)(C) do not include research and development costs of using new materials, as well as performance and other testing (for example, for medical devices). These costs are important factors and should be part of the AA. Further, the Factors in subparts (B) and (C) do not include performance of the selected alternative.

Step 2 (subpart (b)) will require the use of the tools and guidance materials identified in section 69505. It is important to realize that these tools will provide important information, but will not be conclusive regarding the final decision or assessment. Weighting of the factors involved will have a significant effect on the outcome, and only the technical expertise of the manufacturer and assessor will be able to adequately weigh factors in the assessment. As we mentioned previously, there will rarely be a clear-cut “winner” material in this process, and only, after reviewing all the evidence, will the assessors and manufacturers be able to make a final decision based on the totality of the evidence. While the manufacturers will attempt to provide justification to the Department, it is not clear that the Department will agree with this justification, or for that matter, the outcome of the assessment.

Subpart (d), considering additional information, should be performed before an alternative is selected (currently subpart (c)).

The timelines for implementation of the alternative (in several sections, but mostly section 69505.5), are very tight and manufacturers, in many cases, may not be able to implement an alternative in proposed timeframe. For example, communications and medical devices have, on average, a four-year cycle between when a product is first designed to when it is formulated, assembled, and tested for performance and compliance with existing regulations. Further, smaller companies often do not have the “pull” to affect changes in the supply chain; in fact, large companies (our associations represent many of the world’s leading high-tech companies, as well as smaller or medium enterprises) often have trouble affecting changes in the supply chain since many companies are located overseas. This may lead to an outcome where certain globally-available products will not be available for sale in the State of California.

#### **Section 69505.5. Alternatives Analysis Reports**

(a) – The term “sufficient information” is used several times in this section, but is not defined in the regulations. It is not clear how the responsible entity can provide information for an appropriate due date. Section 69505.4(e) states that a responsible entity shall propose regulatory responses as part of the AA, then section 69505.5(a)(4) states that the Department will determine an appropriate regulatory

response. What is the process if the Department disagrees with the Certified Assessor/Responsible Entity proposed response?

(d) – It is very likely that the manufacturer will not have much of this information, and it is unclear why this information would be necessary for an environmental, health and safety alternatives assessment. Manufacturers typically sell to distributors or distribution centers, and they determine what products go where. Additionally, much of this information, especially the supply chain and manufacturing locations, is likely classified as “trade secret” information.

Recommendation:

Remove these reporting requirements from this section. If this information is necessary, the Department can obtain it in the process outlined in § 69506.9.

(f) – The Regulation should not dictate how information is presented in the Alternatives Analysis Reports. It is not possible, in all cases, to present a matrix or even an easily-understood visual comparison. Very complex AAs may not lend themselves to one particular type of information format.

Recommendation:

Simplify section (f) and remove most requirements for how information is to be presented. The Department should consider adding a subpart asking for clarification on a section of the AA, rather than simply asking for more information.

(g) – As mentioned in several sections, determining the relevant comparison factors is a somewhat subjective exercise and depends greatly on technical expertise and knowledge of the industry being assessed. It is not clear what will happen if the Department disagrees with the weighing and comparison of the factors.

(j) – The list of all chemical ingredients is not always available for complex parts and products, or it may be confidential information not available to the responsible party or not relevant to the AA. The further information (subparts 1-6) is potentially a significant amount of information for the manufacturer to prepare and Department to process, which may not be relevant to the AA for the chemical-product pairings. We recommend simplifying this section and paring the information required to the chemical/product information used in the AA and relied upon to make the final assessment.

(k) – As per our general and subsequent comments, it may take several years to complete these sections, and it is not clear that the deadlines in this section are practical. We recommend providing more flexibility, especially for more complex products.

## **Section 69505.6. Department Review and Determinations for AA Reports**

It would seem that this section obviates the need for Certified Assessors in Article 8. If the Department is reviewing all AAs to ensure compliance with this section, it is not clear what role the Certified Assessor will serve in assuring the quality and thoroughness of the AAs.

## **Article 6. Regulatory Responses**

### **Section 69506. Regulatory Response Selection Principles**

As written, this section does not require the Department to consider the five factors listed in subsection (c) when determining which regulatory response may be appropriate, if any. Rather, DTSC is only required to give preference to regulatory responses that provide the greatest level of “inherent protection.” However, less inherent toxicity in a product should not be the only factor DTSC considers; there are many other factors involved when a decision is made to use a particular chemical in a product. Thus, DTSC should be required to consider all five factors listed in subsection (c) by eliminating the permissive language on Page 52, Line 15 and replacing it with “...the Department shall consider all of the following factors.” We believe that reasonable consideration of all five factors prior to imposing any regulatory response will be critical if the program is to be practical, meaningful, and legally defensible. Additionally, the Department should consider existing regulations when determining a regulatory response.

Recommendation:

Add the following line to subpart (c):

(c)(6) Existing regulations for that product

Finally, while we appreciate that DTSC has included a cost-effectiveness consideration in (c)(2), we are concerned that the Department will not have the information necessary to do an effective cost-benefit analysis of the regulatory response.

### **Section 69506.1. Applicability and Determination Process**

We believe that this section should include a minimum timeline for when a regulatory response will be required to be implemented. Given the complexity and significance of the regulatory response options at the Department’s disposal, we believe that regulated entities should be given a minimum of one year(?) after the receipt of the final regulatory response determination notice to implement the regulatory response. This timeline should increase depending on the severity of the regulatory response selected.

### **Section 69506.2. AA Report Supplemental Information Requirements**

As written, we believe that this regulatory response would act as an overly broad and unnecessary mandate on companies, giving the Department the ability to demand any information from a company on any timeline it chooses. We suggest the following changes:

§ 69506.2 (a) – Change to read:

(a) The Department may require a responsible entity to provide, within a reasonable time frame specified by the Department, information supplementary to the Final AA Report...

§ 69506.2 (b) – Change to read:

(b) The Department may require a responsible entity to obtain or develop, within a reasonable time frame specified by the Department, information that is reasonably attainable by the entity to fill one or more information gaps identified in the Final AA Report...

In addition to these changes, we believe that the information demands made by DTSC should be targeted and reasonable, rather than overly broad. Furthermore, once the required information has been provided, that action should fulfill the regulatory response obligation for a reasonable period of time, so that a compliant entity is not continuously required to generate more and more information.

### **Section 69506.3. No Regulatory Response Required**

It is not clear how this section relates to the product sales prohibition (Section 69506.6) and end of life management (Section 69506.8) response options. As currently written, it appears that § 69506.8, and potentially § 69506.6, will act as “default” regulatory responses and will be automatically implemented unless a finding is made that no regulatory response is required under this section. This is due to the language in both sections reading “except as provided in section 69506.3.” For obvious reasons, we believe that automatic triggers for any of the regulatory responses, including product information, will lead to unnecessarily burdensome results. Rather, DTSC should be required to carefully weigh and consider all of the factors delineated in § 69506(c) before deciding to impose any of its regulatory response options.

### **Section 69506.4. Product information for Consumers**

As written, it appears that this regulatory response will be automatically required unless no Chemical of Concern is present above the applicable threshold. This automatic trigger seems unnecessary and could lead to information saturation for consumers on a wide scale. This is especially true given the amount of information required by subsection (a)(1). This requirement also includes some information that the manufacturer may not even have available, such as (a)(1)(C), or that may be considered confidential business information, such as the importer information in (a)(1)(F).

It would also be very difficult to fit this much information on the product packaging, and retailers will not voluntarily provide a placard at the point of sale. As we have stated in prior comments, the physical labeling of products is an outdated and inefficient solution that makes little sense for many types of

products. Research continues to show that beyond immediate hazards, labeling of a product is an ineffective way to warn consumers of potential hazards. Furthermore, information/disclosure requirements should be done in the least restrictive manner possible. Manufacturers should have options to labeling by providing information channels to consumers through the use of websites, product manuals, or other options that make sense for their market and for the potential hazard.

#### **Section 69506.5. Use Restrictions on Chemical(s) of Concern and Consumer Products**

It is not clear how restrictions on the use of consumer products can be enforced. While information on use restrictions can certainly be made available, how would the Department ensure compliance with such restrictions?

#### **Section 69506.6. Product Sales Prohibition**

As stated above, it is not clear how the tie-in to Section 69506.3 would work in practice for the product sales prohibition response option. Additionally, how would the Department know which products contain any Chemical of Concern above the applicable alternative analysis threshold, and which do not? Again, there may not be tests available for determining the presence of a particular material in a product, making these determinations and enforcement challenging.

This section is also made unnecessarily burdensome by allowing the Department to still prohibit the sale of a product even if no viable alternatives exists (see subsection (d)(1)), and by requiring responsible entities to notify DTSC if their product does not contain a Chemical of Concern.

#### **Section 69506.7. Engineered Safety Measures or Administrative Controls**

We would suggest that this section use the term “accessibility” rather than “integrally contain” in subsection (b), as there are defined tests for accessibility, making it a more objective standard for compliance. Thus, page 57, subsection (b), line 16 would read: “limit accessibility to the Chemical(s) of Concern within the structure of the product or limit...”

Additionally, we believe that there needs to be thresholds for presence under subsection (b)(1) as Chemicals of Concern, metabolites, or others may be naturally occurring or have multiple metabolites. Simply requiring “presence” is too ambiguous of a standard to be useful here. Also, as written, presence in a single building would be sufficient to trigger administrative control under (b)(2), which we think is unnecessarily strict.

#### **Section 69506.8. End-of-Life Management Requirements**

As stated earlier, it appears that this regulatory response will be automatically imposed unless the Department finds that there is no need for any regulatory response under § 69506.3. Automatically requiring end-of-life management requirements would lead to unnecessarily burdensome results as

comprehensive product stewardship plans are very significant undertakings – logistically, financially, and otherwise – that should not be imposed absent careful consideration of all factors delineated in § 69506(c).

In addition, a one year time frame given in subsection (a)(2) is far too short for entities to implement the complex take-back schemes envisioned by this section, and it is unclear what financial guarantees, if any, would be adequate or available to entities under (a)(2)(A)(7). An additional concern is that this section does not differentiate between Business to Business (B2B) markets and consumer markets; there are viable markets for B2B recycling in many instances and the regulation should not undermine the free markets here.

The report required under (a)(2)(D) is also problematic. First, information on state sales and recycling is likely not available – most sales are done through distributors and manufacturers have no way to track what is sold in state. Additionally, and especially in the electronics industry, there is a vibrant post-consumer market, which would also make tracking recovery very difficult. And for durable products especially, which have lifespans of several years, the amount of goods recovered in a given year will have no relation to the amount of goods sold, which could give the impression to the Department that a program is performing poorly when in fact it is not.

Finally, it is unclear how a manufacturer might be able to prove to DTSC that an end-of-life management program is not feasible under subsection (d), though we agree that responsible entities should have the opportunity to show why they should be exempt from the requirement.

#### **Section 69506.9. Advancement of Green Chemistry and Green Engineering**

This section states that DTSC may “require” a manufacturer to conduct research and development, or fund a challenge grant, to design, improve, reduce the cost of, or increase the market penetration of, a safer alternative to a Priority Product. Since any given manufacturer might not have the resources to undertake such project, or might believe that such projects are not likely to be successful, a manufacturer should always have the option of discontinuing manufacture of the Priority Product. Section 69506.9 should be amended to provide explicitly that a manufacturer can choose to discontinue manufacturing a Priority Product instead of complying with any requirement issued pursuant to this section.

Additionally, many companies are engaging in research and development to achieve the goals specified in subparts (a) – (d), independent of the mandates in this regulation. These companies should be given credit for their independent efforts as it relates to this regulatory response, and any further mandated funding of R&D needs to come with IP protection for the responsible entity.

### **Section 69506.10. Regulatory Response Selection and Re-Evaluation**

As written, it is not clear what other situations DTSC is referring to in subsection (a), or why this section is needed to begin with. This section seems to remove any of the constraints imposed by earlier sections by stating that DTSC “may impose one or more regulatory responses ... to situations other than those specified in those section.” If that is the case, what could the Department not impose as a result of this section? We would request clarification on this point.

Additionally, the term “periodically” needs to be further defined or clarified in subsection (b). It would be unnecessary and burdensome to review regulatory responses too frequently. Entities need certainty with the responses they are required to comply with in order to do business.

### **Section 69506.11. Exemption from Regulatory Response Requirements**

As written, this section appears duplicative of work that the Department should have presumably already completed: the determination of conflicting or duplicative regulatory programs. If the product is already covered by California or other regulatory programs elsewhere, the product should already be exempt from these requirements. The responsible entity should not have to do an alternatives analysis and then put in a formal request to DTSC for exemption to demonstrate that a conflict exists with other regulatory schemes. That determination should have already been made.

We would suggest that a responsible entity be able to request and receive exemption for compliance with international law, such as RoHS or REACH, provided that the manufacturer can show compliance and that the international law will also provide health and environmental benefits.

### **Section 69506.12 Regulatory Response Report and Notifications**

As written, we believe this section is very problematic and fundamentally ignores the realities of supply chains and commerce. Manufacturers rarely sell directly to a retailer and thus will not be able to identify the retailers required to comply with subsection (a). We would suggest rather that the manufacturer notify whoever it is they are directly selling the product to if it is reasonably likely that the product will be sold in California. Then, the entity selling or distributing the product would be obligated to notify the appropriate retailers.

We believe the regulatory response notice to the Department required under subsection (c) is unnecessary, as DTSC should assume but confirm compliance as needed, such as by requesting compliance documentation.

## **Article 7. Dispute Resolution Proecesses**

### **Section 69507. Dispute Resolution**

It is not clear why articles 2, 4 and 10 are not subject to dispute resolution. We would think that the DTSC would welcome the opportunity to informally arbitrate any decision made pursuant to the

Regulation. We would think an information dispute process would help these articles; otherwise injunctive relief through the courts would be the only process open should a dispute arise. We suggest allowing all Articles to have some sort of administrative dispute process.

### **Section 69507.1. Informal Dispute Resolution Procedures**

We submit that allowing only 30 days to dispute an action, especially notice on the Department's website, is inadequate. In many cases, it may take 30 days for a responsible entity to realize they are involved and decide to dispute a posting. We suggest at least 90 days for this initial time.

### **Article 8. Accreditation Bodies and Certified Assessors**

ITI, TechAmerica, CEA, and SIA strongly assert that the Certified Assessor process as described in Article 8 will not serve to meet the goals of the Green Chemistry Initiative to ensure that 1) the alternative assessments are conducted by a person with all of the expertise necessary to adequately complete an assessment, and 2) that assessments will be done within the expected requirements for compliance with the law, thoroughness, and scientific rigor. For the reasons described in comments to previous sections and below, we urge the DTSC to remove Article 8.

Simply put, the Certified Assessor requirement will increase the costs to do the AAs, with absolutely no benefit. Most small companies will need to hire a third-party assessor, and larger companies will likely assume the expense of getting one or more of their technical experts certified. Most certified assessors will not have the specific product knowledge, especially if they are not experts in the industry they are trying to assess, to perform an assessment. Simply requiring a bachelor's degree in a scientific field and training on the requirements of these regulations will not ensure that the assessors will have the knowledge base to adequately perform an assessment. The assessor must have knowledge of the tools being used to perform the assessment (which will vary depending on the type of material and product assessed), knowledge of the industry being assessed, and the expertise to be able to weigh the factors and assess the information used to perform the assessment. No certification program will ever be able to provide this level of expertise.

As we have mentioned previously, the use of third-party certified assessors will likely create potential legal issues. For example, who will be liable for any material use decision based on the outcome of an assessment? What happens if the manufacturer disagrees with the assessor? What if multiple assessors are used (either in different manufacturers of the same product, or even within a single assessment) and the assessors disagree on the optimal outcome? Who will resolve any conflicting findings?

Recommendation:

Delete Article 8. The Department reviews all submissions for compliance with the regulations in section 69505.6 and has provided for a process to audit any AAs submitted under Article 9. We believe this is adequate protection to ensure that the assessments are done correctly, and the Department has the ability to review the AAs in depth for compliance, information quality and adequacy of the analysis.

## **Article 10. Trade Secret Protection**

### **Section 69510. Assertion of a Claim of Trade Secret Protection**

The electronics industry believes that a reasonable protection of confidential business information (CBI) is critical to innovation and competition in the market. As mentioned earlier, the Proposed Regulation would require manufacturers to supply a substantial amount of information to the DTSC, including sales and manufacturing process information. The submittal of such a broad range of potentially sensitive information increases the likelihood and frequency that a manufacturer may have to rely upon the regulation's trade secret provisions in order to safeguard its CBI.

Under Section 69510(a), a claim for trade secret protection will involve the submittal of extensive supporting information to the DTSC in order to substantiate its need for trade secret protection. A disagreement from the DTSC in the trade secret claim would mean that the manufacturer would need to cure the perceived deficiencies in the trade secret claim or seek judicial review in order to prevent the CBI from being released to the public (Section 69510.1).

This resource-intensive CBI claim process strongly emphasizes the need for the Department to carefully consider what information it truly requires from regulated entities throughout the Regulation. Thus, we urge the Department to limit submission requirements only to that information which is absolutely necessary for DTSC to implement the Regulation. This will help reduce unnecessary compliance burdens and help ensure that CBI is properly protected.

Further, this section of the regulations should focus on the interrelationship of the new Safer Consumer Products law with existing California laws on trade secrets. California Civil Code § 3426.1 provides:

(d) "Trade secret" means information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- (1) Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- (2) Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Therefore, in order to establish that information submitted is a trade secret under California law, one would need to show that: (1) it has independent economic value, actual or potential, because it is not known to others; and (2) it is the subject of efforts to maintain its secrecy that are reasonable under the circumstances. The determination (whether or not information claimed to be trade secret is to be released) by DTSC under California Health and Safety Code §25257(d) should logically begin by looking at those two questions. While it seems that the gist of each of these two questions is addressed in subpart (a) of the document, subpart (b) requires, by itself, the submission of a large quantity of information, on top of the already large quantity of information that is being requested by the Proposed Regulation. Further, if any of the Trade Secret claims themselves are claimed to be Trade Secret, the entire process of subparts (a) must be submitted as per subpart (b), setting up a potential feedback loop of data submissions to the department. In particular, subparts (a)(4-8) will almost invariably involve trade secret information.

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The exclusion of all chemical identity information in subpart (f) is overly broad due to the broad definition of “hazard trait” found in OEHHA’s supporting regulations. For example, a chemical with the hazard trait of “irritation” cannot be claimed as a trade secret, even if it is not being assessed for that trait. Often, chemical identity is the most closely guarded trade secret, and, as drafted, the Proposed Regulation will substantially reduce the ability to protect such intellectual property.

For subpart (g), how does a manufacturer establish a chemical use is a “new use?” Proving that a chemical has never been used is difficult.

#### **Section 69510.1. Department Review of Claims of Trade Secret Protection**

As mentioned in our comments to section 69507, it is not clear why the DTSC would not subject these determinations to an agency review process. We appreciate that the DTSC has included in subpart (d) that the Department may not disclose information until a court proceeding is finished; however we are still concerned with the timelines, in particular subpart (b)(2). It is unlikely that a manufacturer will be able to respond or file an action in 30 days.

#### **Conclusions**

ITI, TechAmerica, CEA and SIA wish to thank the Department for its ongoing work on the Proposed Safer Consumer Product regulation, and feel that the proposed regulations contain several significant improvements compared to previous drafts. However, we are very concerned with the lack of specificity in several sections of the regulations, the immense data submission burdens, the required use of certified assessors, and the very weak trade secret protections offered in the draft regulations. We share the Department’s goals of a meaningful and workable regulation, but unfortunately feel that the proposed regulations contain several sections, as outlined above, that would make these difficult for industry to interpret and meet, as well as for the Department to enforce. We look forward to continuing to work with the DTSC to finalize a workable set of regulations in a manner that will focus on the chemicals and products that pose the greatest risk.

If you have any questions, please do not hesitate to contact Chris Cleet at (202) 626-5759 or [ccleet@itic.org](mailto:ccleet@itic.org), or Robert Callahan at (916) 443-9088 or [robert.callahan@techamerica.org](mailto:robert.callahan@techamerica.org).

Sincerely,

## GCREgs@DTSC

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**From:** dennis <ddtap@comcast.net>  
**Sent:** Monday, October 01, 2012 7:49 AM  
**To:** GCREgs@DTSC  
**Subject:** consumer labeling

**Categories:** Comment

I would hold up to criminal contempt any public officer who did not complete the job set to him. Complete the list of "chemicals of concern" so that the public may know of them and may avoid them.

Sincerely, Dennis Tapley, 



October 11, 2012

Ms. Debbie Raphael  
Department of Toxic Substances Control  
c/o Krysia Von Burg, Regulations Coordinator ([gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov))  
P.O. Box 806  
Sacramento, CA 95812-0806

RE: Proposed Regulations – Safer Consumer Product Alternatives

Dear Debbie:

Many thanks to you and the entire DTSC team for your long and thoughtful effort to develop the Safer Consumer Product Alternatives Regulations. DTSC has constructed a practical regulatory framework for meaningful implementation of AB 1879 and SB 509. The proposed regulations, which are consistent with scientific advice from DTSC's Green Ribbon Science Panel, have a solid scientific basis.

Although the regulations appear ready to implement, I suggest that DTSC consider the following minor changes to improve DTSC's capability to address non-human environmental problems.

#### **A. Chemicals of Concern – Environmental Toxicants**

One of the challenges in developing these regulations has been identification of scientifically robust lists of chemicals of concern for the non-human environment, since relatively few such lists exist. In consultation with scientists in the water quality community, I have identified two such lists that I recommend DTSC consider adding to Section 69502.2(a). Both lists have an important difference from the lists of water pollutants harmful to aquatic life in the current regulations—these lists better reflect current priorities and both are regularly updated to reflect new scientific information.

1. California's Clean Water Act Section 303(d) list – This is the list of the state's identified water pollution problems. It is updated regularly on the basis of new scientific data. It is a regulatory list based on scientific data that is vetted through public review, Water Board vote, and U.S. EPA approvals. The current version of the list is available from the State Water Board.<sup>1</sup>
2. The European Union's list of Priority Substances under the Water Framework Directive – This is the European Union's list of chemicals that pose the greatest

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<sup>1</sup> [http://www.waterboards.ca.gov/water\\_issues/programs/tmdl/integrated2010.shtml](http://www.waterboards.ca.gov/water_issues/programs/tmdl/integrated2010.shtml)

threats to water quality. This regulatory list is based on scientific information, is vetted through a public review process, and is adopted by a regulatory agency. It is updated regularly. The current version of this list is in Annex II of the Directive on Environmental Quality Standards (Directive 2008/105/EC).<sup>2</sup>

Both of the above lists meet all of the chemical list criteria specified in the Initial Statement of Reasons.

## **B. Initial Priority Products List**

Most of California's water pollution problems are not associated with the types of pollutants on the lists in Section 69502.2(a)(1), which list human persistent, bioaccumulative toxicants (PBTs) and human carcinogens, mutagens, and reproductive toxicants (CMRs). Using these human pollutant lists to constrain the Initial Priority Products List (Section 69503.3(g)) would prevent the state from tackling important water pollution problems during initial implementation of the regulation.

To ensure that the state can immediately address California's water pollution priorities, DTSC should modify Section 69503.3(g) to add presence of a chemical of concern on the Clean Water Act Section 303(d) list as sufficient basis for selection of an initial priority product. This change would add a small number of pollutants (fewer than a dozen) to the initial eligible list and would ensure that the state's most common non-pesticide chemical water pollution problems (e.g., copper and zinc) can be addressed.

## **C. Regulatory Response Selection**

I commend DTSC's decision to add regulatory response selection principles (Section 69506). This type of guidance has proven invaluable in other regulatory programs.

Two slight modifications of these principles would allow DTSC to better balance non-human environmental protection in its decisions:

- Amend Section 69506(c)(3) to provide for consideration of burdens on all types of organizations. The current list excludes organizations responsible for natural resources, water quality, and wildlife. Examples of the types of organizations that may experience burdens are other government agencies (such as California State Parks, California Water Boards, California Fish & Wildlife, Caltrans, local governments, and municipal wastewater treatment plants) and non-profit organizations (such as non-profit land stewardship and wildlife conservation organizations).
- In addition to sensitive subpopulations, add sensitive ecosystems to Section 69506(c)(4).

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<sup>2</sup> [http://ec.europa.eu/environment/water/water-dangersub/pri\\_substances.htm#dir\\_prior](http://ec.europa.eu/environment/water/water-dangersub/pri_substances.htm#dir_prior)

On the basis of my experience with agency decisions about other consumer products, I encourage DTSC to add another principle to Section 69506(c) that directs the Department to minimize the time frame required for achieving human and environmental protection.

#### **D. Presentation of Alternatives Assessment Results**

Although Alternatives Assessment should be summarized in a matrix, this should not be the only way that results are presented. The analysis will not be transparent without accompanying text. To address this, I suggest a minor revision to Section 69505.5(f)(1)(B) (page 47 line 14):

“(B) The information required under subparagraph (A) must be ~~presented~~ summarized in a matrix, or other format, that provides the reviewer with an easily understood visual comparison of the chemicals and their adverse impacts.”

#### **Conclusion**

It has been an honor to have the opportunity to serve on the Green Ribbon Science Panel and to assist DTSC with the development of its landmark program to protect human health and the environment from pollutants in consumer products. I would be pleased to continue to provide whatever support I can toward helping you create a practical, meaningful, and scientifically robust regulatory program.

Sincerely,

/s/

Kelly D. Moran, Ph.D.  
President

Test & Measurement Coalition Comments on Proposed  
Safer Consumer Product Regulations of July 2012

**Introduction:**

The Test & Measurement Coalition represents an ad-hoc group of global companies active in producing electronic industrial test and measurement products (including professional and laboratory types) which are classified as Category 9 industrial monitoring and control equipment in the European Union RoHS and RoHS 2 (Recast) Directives. The Coalition includes six leading companies in the sector including Agilent Technologies, Anritsu, Fluke Corporation, Keithley Instruments, National Instruments, and Tektronix. We estimate the Coalition membership represents roughly 60% of the global production of industrial test and measurement products.

The Test & Measurement Coalition has not previously provided comments on informal drafts of the California Safer Consumer Product Regulations as it was not understood to impact the industrial manufactured products sector. We are now compelled to provide our comments on the draft regulations in light of the definition of 'consumer' inherent in the scope of products to be covered by the regulations. The Coalition members are very concerned about the impact the overly-broad definition of the terms 'consumer' and 'consumer product' in the regulations will have on the test and measurement industry and consequently on the competitiveness of downstream customers who require test and measurement equipment to enable innovation in design, quality in manufacturing and accuracy in data acquisition.

The design and qualification process, volume of product placed into commerce, product life, and customer base related to the industrial test and measurement sector are very different than those for typical manufactured consumer products. They cannot be treated in the same fashion as manufactured products which enjoy a much more rapid design and manufacture cycle. Additionally, due to the small volume of product involved, potential impacts to consumer safety from industrial test and measurement equipment in the sector are vanishingly small when compared to the volume of consumer products in the market.

We therefore respectfully request that industrial test and measurement equipment be excluded from the scope of the Safer Consumer Product Regulations as was done for professional medical devices, which have similar design imperatives.

### **General Comments:**

We believe the proposed regulations, as they stand, do not represent the input or concerns of the broad base of small, medium and large enterprises manufacturing industrial test and measurement products which are not typically deemed 'consumer' products under United States law. Products not falling under the aegis of the Consumer Product Safety Commission, such as industrial test and measurement equipment, typically have unique design, qualification and regulatory requirements, smaller volumes of product placed into commerce, longer product life, and a highly trained customer base as compared to those for typical manufactured consumer products.

As such, they should not be treated in the same way as manufactured products which enjoy a much more rapid design and manufacture cycle — a fact that has been acknowledged in the European Union's treatment of industrial test and measurement equipment during the development of the Directives concerning the use of certain hazardous substances in electrical and electronic equipment (RoHS & RoHS 2.) Industrial test and measurement equipment, as part of the industrial monitoring and control category, has been granted the longest transition time — 15 years from publication of the RoHS Directive — to achieve removal of the six original restricted substances. The transition requires this extended timeframe as well as many technical exemptions allowing continued use of the six substances in specific applications which have been granted exclusively for use by the monitoring and control, and medical sectors.

Without such a long transition for the removal of the substances, there is significant risk of forcing premature withdrawal of products that are vital in supporting research and development, manufacturing, and monitoring of core infrastructure required to maintain public or environmental safety (e.g. telecommunications systems, industrial emergency shutdown systems.) Industrial test and measurement equipment typically enjoys a long life and customers may mandate that the same product be available for many years in order to support drop-in replacement in systems that can't be easily redesigned to accommodate new equipment. Unanticipated withdrawal of a product from the California market could be devastating in such circumstances.

Similarly, the same product may move in and out of commerce, sometimes for many years, under leasing arrangements which are necessary for many small and medium enterprises who could not otherwise afford the high price of specialized test and measurement equipment required to support their business needs. If products must be withdrawn from availability for lease due to substance restrictions, there would be significant negative impact on the both the leasing companies and their small and medium-sized clients.

Recalibration, reuse in part or in whole, and refurbishment are also utilized to extend the life of test and measurement equipment and its availability across the spectrum of customers. Inclusion of test and measurement equipment in the scope of the proposed Safer Consumer

Product Regulations puts all these activities at risk with no proportional health or environmental benefit.

It should also be noted that industrial test and measurement equipment manufacturers must spend a disproportionate amount of resources to assure availability of existing product, when compared to the consumer electronics sector, by counteracting the withdrawal of needed components from the supply chain due to the extended longevity of the product's design. This is usually handled by performing a lifetime buy of the component in question or a small-scale redesign to substitute a different component. A natural consequence of this business process is that there will be some number of components for which it will be very difficult, costly or impossible to obtain substance information with no continuing support from the original manufacturer of the part.

Additionally, this diversion of design engineers toward sustaining work means that there are fewer resources available to work on the design of new products or change designs to eliminate substances. Any redirection of design resources toward substance elimination will therefore have a negative impact on innovation in the industrial test and measurement industry and consequently on the competitiveness of downstream customers working to extend performance of their products to the next level. Test and measurement equipment capabilities must stay ahead of the technological curve of the downstream industries in order to support their design work.

For these reasons, as well as the procedural and technical reasons outlined in more general electronics industry commentary provided by various trade associations, we believe the Safer Consumer Product Regulation is not a suitable instrument for regulating substances of concern in industrial test and measurement equipment. We therefore request that industrial test and measurement products be removed from the scope of the regulations as has been done for professional medical devices, which have similar design constraints.

**Specific Comments by Section:**

**Section 69501. Purpose and Applicability**

As noted in the general comments, the regulation should exclude industrial test and measurement products explicitly. We suggest modifying §69501. (b)(2) with an additional sentence as follows:

(2) This chapter does not apply to any product that is exempted from the definition of "consumer product" specified in Health and Safety Code section 25251, or to any product that is placed into the stream of commerce in California solely for the manufacture of one or more of the products exempted from the definition of "consumer product" specified in Health and

Safety Code section 25251. This chapter does not apply to any product that is a manufactured test and measurement product that is not subject to the authority of the Consumer Product Safety Commission.

### **Section 69501.2 Definitions**

The 'Consumer Product' definition requires modification to remove industrial test and measurement equipment from the meaning. We suggest the modification of point §69501.2 (a)(22)(A)1 to align it with the revised text for §69501 (b)(2):

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

1. A "consumer product" as defined in Health and Safety Code section 25251; excluding manufactured test and measurement products that are not subject to the authority of the Consumer Product Safety Commission;

### **Conclusions**

The members of the T&M Coalition wish to thank the Department for considering our comments and suggestions regarding these regulations. We are very concerned with the unintended consequences that could arise due to premature withdrawal of industrial test and measurement equipment from California commerce if it were to be subject to the requirements of the Safer Consumer Product Regulations. We therefore respectfully request that industrial test and measurement equipment be removed from the scope of the regulations.

If you have any questions on our submission, please do not hesitate to contact the T&M Coalition for further information.

On behalf of the Coalition,



Martin Baggs  
Tektronix, Inc.



FRANK SCOTTO  
MAYOR

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# CITY OF TORRANCE

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October 10, 2012  
SENT VIA U.S. MAIL &  
ELECTRONIC MAIL [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

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

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

Dear Director Raphael:

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

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

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

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

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

Sincerely,

Frank Scott  
Mayor, City of Torrance

FS:maw  
cc: City Council Member  
LeRoy Jackson, City Manager  
Robert Beste, Public Works Director  
Alison Sherman, Waste Management Coordinator

**From:** Rory <roaringrory@cox.net>  
**Sent:** Tuesday, October 09, 2012 8:20 AM  
**To:** GCREgs@DTSC  
**Cc:** Rory  
**Subject:** Safer Consumer Product regulations  
  
**Categories:** Comment



TO: Ms. Von Burg,

I am writing you this letter to let you know my concern about the Safer Consumer Product regulations and green products use. If this adoption regulation takes place it may cause many small businesses and even large businesses to suffer financially. Please be cautious in adopting these new regulations.

Thank you.

Rory Townsley



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October 11, 2012

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

**Subject: Comments on the California Department of Toxic Substances Control – Proposed Regulation: Safer Consumer Product Alternatives**

Dear Ms. Von Burg:

Below please find a summary and detailed discussion of key concerns from the Toy Industry Association (TIA) regarding the Department of Toxic Substances Control (DTSC or Department) Proposed Regulations for Safer Consumer Product Alternatives (Proposed Regulations) under Assembly Bill 1879 and Senate Bill 509 (2008). We remain concerned about the current structure and requirements of this proposed regulation and believe that the current draft is unworkable.

TIA is disappointed to find that these regulations lack the transparency and predictability necessary to both operate and achieve the goals of a program of this magnitude, and would appreciate the opportunity to work with DTSC staff to make changes that will yield a truly workable regulatory program. TIA strongly believes that with significant and substantive redrafting of these regulations, it is possible to create a regulatory proposal that protects human and environmental health, without catastrophic effects on commerce and product innovation.

These comments are in addition to, and incorporate where relevant, previous comments submitted to the Department by TIA on July 20, 2010, November 1, 2010, December 3, 2010, December 30, 2011 and May 30, 2012. TIA continues to urge the Department to seriously consider compromise and progress toward reaching a workable solution that is consistent with other states, as it is difficult for our industry to see a path forward toward workable Green Chemistry Regulations without consistency between states on key issues.

TIA is a not-for-profit trade association representing more than five-hundred (500) toy makers, marketers and distributors, large and small, located throughout North America. TIA's members account for approximately 85% of the annual U.S. domestic toy market of \$21.6 billion, according to research from the NPD Group. Additionally, Toy Industry Association members employ more than 32,000 employees in California with a direct economic impact of more than

\$6 billion to the state. The Toy Industry Association and its members have long been leaders in toy safety. In this role, we develop safety standards for toys, working with industry, government, consumer organizations, and medical experts. The U.S. risk-based standards are widely recognized and used as models around the globe. One of our missions is to educate industry on these standards, and to educate parents and caregivers on choosing appropriate toys and how to ensure safe play.

Below are fundamental concerns with the proposed Rule that TIA believes must be addressed before a workable regulation can be adopted:

**It is imperative that DTSC take the most effective and least burdensome approach to meeting its mandate to adopt regulations.** Addressing the following issues would create a more effective and workable program, while minimizing the burden these regulations will place on the California and national economies:

- **Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2]:** As DTSC acknowledges in their “Initial Statement of Reasons” (ISOR) [Section 69503.2], there is little to no exposure to a “Chemical of Concern” (CoC) from inaccessible components. In order to provide appropriate focus to the prioritization process, there is a need to define “inaccessible components” and remove these components from prioritization. This approach is consistent with California’s statute – § 25252(a) of the statute directs DTSC to consider potential exposure and exposure pathways which supports the exclusion of inaccessible components from coverage by the regulation. It is also consistent with similar laws regulating the presence of chemicals in children’s products in Washington State, Maine and on the federal level under the Federal Hazardous Substances Act and the Consumer Product Safety Improvement Act.

*TIA proposes adding new language in Section 69503.2 stating that “The Department shall not consider the presence of a chemical of high concern which is solely contained within inaccessible components as a basis for naming or selecting a priority product, unless the Department finds scientifically credible, peer-reviewed data indicating that significant adverse impacts to human health or the environment have resulted from exposure to inaccessible components at any time during the life cycle of the product.”*

We further suggest that if a definition of “inaccessible” is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

- **Link Between Priority Products and Potential Exposure [Section §69503.2]:** When determining priority products, it is critical that DTSC demonstrate both an exposure pathway AND that the pathway for a product is a significant contributor to a

cited human and/or environmental exposure. Products that are a minimal contributor to exposure should not be listed as a “Priority Product.”

Currently, the regulations outline specific factors DTSC will use to evaluate and prioritize Priority Products, which include “reliable information regarding exposures.” The ISOR states relevant information may include monitoring data, environmental media data and biomonitoring data. What is glaringly absent is a requirement for DTSC to establish even the most tenuous connection between a specific product and the observed potential for exposure. TIA is interested to know on what basis DTSC determines that a specific product is a significant contributor to the pollution or bioburden, or even that it contributes at all? The current stance of the Department places the burden of proof (to prove a negative) on those being regulated, rather than the Department having a duty to establish with a reasonable degree of certainty that a specific product is a significant contributor to the exposure.

Additionally, the Regulations give consideration to “Intended product use(s)” [Section 69503.2]. However, when determining priority products based upon exposure, it is essential that the Regulations specifically stipulate that the exposure evaluations apply to “reasonably foreseeable” exposures from a product during reasonably foreseeable processing, use, and end-of-life management for the product. An understanding of “real world” concentrations, routes of exposure, and existing mechanisms to prevent harm must be built into these Regulations.

- **Intent/Definition of “Highly Durable Products” [Section §69503.4]:** After discussions with DTSC staff, it is clear that what was intended here is to denote a class of products which are “complex” rather than “highly durable” in order to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is arbitrary and capricious to summarily discriminate against children’s product makers by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children’s products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.
- **Alternatives Assessment (AA) Threshold Exemption [§69503.5]:** The overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department and manufacturers will be overwhelmed by unnecessary paperwork under this provision, and consumers will be overwhelmed with information that is likely to be confusing and misleading. The process requires the release of proprietary

data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it has a Priority Product that contains a Chemical of Concern below the AA threshold level. The Department could then request additional information if needed. Notifying entities should be allowed to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

**DTSC should develop a transparent and predictable regulatory framework in order to establish an effective and workable program.** The narrative, rather than prescriptive, approach in these regulations creates an enormous burden of ambiguity and uncertainty for those required to comply, in order to provide DTSC with “maximum latitude and flexibility.” **It is a basic tenet of good regulation that those being regulated must understand what is being regulated and be able to predict the effect of that regulation on their products; in this the Department has so far been unsuccessful.** Addressing the following concerns would help to achieve the transparency and predictability needed for a workable program:

- **Regulatory Duplication Applicability [Section §69501]:** Per the mandates of AB 1879, products where another federal or California State regulation addresses the same risk of injury or environmental threat that has resulted in DTSC prioritizing a chemical or product, must be excluded from further duplicative regulation. Unfortunately, DTSC deleted this exclusion from the “Purpose and Applicability” section (per the October 2011 draft). Regulatory duplication is given consideration during the product prioritization process under the current proposal. However the exclusion must be maintained from the onset of the regulations, not just as a product prioritization factor.

In addition, this concept must be carried through consistently throughout the regulations, including the requirement of Alternatives Analysis (AA) and regulatory response considerations in the AA. If an AA has been completed or is in progress under another state’s regulatory program, then the Department should not require an additional AA, but rather require supplemental information, if necessary. If end-of-life management is already regulated in California, or by the federal government, it is duplicative to include such management in a regulatory response required under this Chapter. The Department should acknowledge that certain other regulatory programs, combined with this Chapter, will provide complete life cycle management of the exposure risks for Chemicals of Concern (CoC) in Priority Products in California.

- **Define Contaminant & Intentionally-Added [Section §69501.1]:** As “contaminant” is referenced in Section 69503.5 of the proposed regulations and is a recurring concept in the ISOR, these regulations should provide a clear definition of contaminant and, in contrast, intentionally-added chemicals. Additionally, whether a chemical is an intentionally-added ingredient or a trace contaminant should impact how an AA threshold is established. Specifically, in a manner that is consistent with Washington State, a trace contaminant or an unintentionally added chemical should be considered differently in setting the AA threshold level.
- **Alternatives Analysis Threshold [Sections §69503.5]:** The Regulations do not provide a clear and predictable process for how AA threshold levels will be determined. Instead, the Regulations provide that the Department may raise or lower a previously established AA threshold level, which creates future uncertainty. TIA believes it is critical to have predictability, and urges DTSC to consider approaches consistent with Washington State and Maine that set clear threshold levels and consider whether a chemical is intentionally-added or is a contaminant in setting the AA threshold level. Additionally, the Regulations do not address whether an unintentionally-added ingredient or a trace contaminant impact AA threshold.
- **Alternatives Analysis [Article 5]:** Alternatives assessment is core to developing safe consumer products and TIA supports a pragmatic and science-based approach. TIA believes the AA Industry Coalition’s “Product development and improvement paradigm” (submitted to DTSC on October 8, 2012) is a solid basis for an appropriate framework. TIA shares the concerns noted in the comments from the European Union (EU) that requirements in the draft Regulations for conducting an AA are highly complex, both technically/content-wise and administratively, and DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate.
- **Trade-Related Issues [Articles 8 & 10]:** The Regulations as currently drafted have the potential to negatively impact trade. As noted in the comments from EU a proper economic analysis has not been completed on these regulations as was conducted by the EU, at the request of the United States and others, before REACH was adopted. The EU comments also point to potential issues with Article 8 setting up a highly unique accreditation and certification scheme that is not recognized beyond State boundaries. TIA shares these concerns, and recommends accreditation by an International Laboratory Accreditation Cooperation (ILAC) – Multilateral Recognition Arrangement (MLA) signatory which is accredited to ISO 17021 be sufficient for the certification of assessors.
- **Confidential Business Information [Article 10]:** Additionally, since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected (Article 10). The nature of the data required to be submitted - once a priority product and chemical

concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. Moreover, Confidential Business Information, which may not fall within the definition of “trade secrets,” should also be protected.

In addition to the key issues noted above, we present in this letter a section-by-section analysis of specific elements within the Proposed Regulations that are problematic. TIA hopes that these comments are helpful to the DTSC as the regulations continue to be revised.

## Section Comments

### **Section 69501.1 Definitions**

**“Accessible Component”** – For assembled products there is a need to define “accessible components”; which also should be referenced in several key places in the regulation to properly focus these regulations and resulting compliance requirements on those components for which there is a likelihood of exposure. Both the terms accessible and inaccessible component are critical to focusing these regulations on actual potential for exposure.

**“Adverse Ecological Impact”** – This definition contains several subjective terms that lack standards and clear definition for determining an actual adverse impact. Specifically, “Deterioration or loss of environmentally sensitive habitats” and “changes in ecological communities” are terms that lack clear definition and exposition regarding how the DTSC will evaluate these impacts.

**“Contaminant”** - There is a need to define “contaminants”; which is referenced in Section 69503.5 (c)(1)(A) & (C) of the proposed regulations, and is a recurring concept in the ISOR. TIA recommends the following definition; which is identical to Washington State’s WAC 173-334-040:

*"Contaminant" means trace amounts of chemicals that are incidental to manufacturing. They serve no intended function in the product component. They can include, but are not limited to, unintended by-products of chemical reactions during the manufacture of the product component, trace impurities in feed-stock, incompletely reacted chemical mixtures, and degradation products.*

**“Homogenous Material”** – This term is difficult to define and has been problematic in the EU RoHS Directive. Therefore, we suggest removing the definition of “Homogenous Material” from the regulations. We agree that the Department needs the ability to set threshold levels at the material level, rather than the part or component level, but this can be addressed in the definitions of “component” and “consumer product.” TIA recommends the following definitions:

*(21) “Component” means a uniquely identifiable part, piece, assembly, subassembly, or a material within a part, piece, assembly, subassembly, of a consumer product that:*  
*(A) Is required to complete or finish an item*

*(B) Performs a distinctive or necessary function in the operation of a product or part of a product*

*(C) Is intended to be included as a part of a finished item*

*(22)(A) "Consumer product" or "Product" means any of the following:*

*1. A "consumer product" as defined in Health and Safety Code section 25251;*

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

**"Inaccessible component"** – For assembled products there is a need to define "inaccessible components"; which also should be referenced in several key places in the regulation to prevent the regulations from overreaching and focusing on components where there is no reasonable likelihood of exposure. We further suggest that if a definition of "inaccessible" is deemed necessary and desirable, that the current standard in use by the United States Consumer Product Safety Commission, found at Title 16, Code of Federal Regulations, Parts 1500.48 and 1500.49 be adopted.

**"Intentionally-added chemical"** - There is a need to define "intentionally-added chemicals." TIA recommends the following definition; which is identical to Washington State's WAC 173-334-040:

*"Intentionally added chemical" means a chemical in a product that serves an intended function in the product.*

#### **Article 1, Section 69501.5 – Availability of Information on the Department's Website**

**AA Threshold Exemption Notification** – As stipulated above and below, to require companies to submit the current proposed AA threshold exemption is unworkable both for the reporter's and Department's workload and it is not necessary for the stated purpose of advising DTSC. The sole purpose in creating a threshold is because it has been determined that a Chemical of Concern below that level does not pose a concern to human health or the environment and should not be prioritized. Further, notification of the fact that a company has provided a threshold exemption, in the eyes of the public, would equate to a black list of products and would require disclosure of potentially confidential information, with no public benefit. Of greater concern is that competitors could glean confidential business information from such reports; thus, chemical identity must be allowed to be kept confidential in such cases

#### **Article 2, Section 69502.2 – Chemicals of Concern Identification**

**(a) Initial Chemicals of Concern List and (b) Additions to the Chemicals of Concern List** – The inclusion of such a broad list of chemicals of concern (CoC), that is estimated to contain 1,200 chemicals, does not provide predictability and certainty to companies. There must be a clear safety-based approach to prioritizing chemicals of concern within these regulations. This is the basis of international chemical regulations; such as the European Union REACH process and the Canadian Domestic Substances List program. Additionally, states like Maine and Washington State have adopted step-wise processes for prioritizing chemicals. While all

stakeholders may not agree on the chemicals selected at each prioritization step, this process is necessary to providing predictability and direction to the market-place. Finally, Alternative Assessments must not fall into the same trap, a rigid prohibition on replacing a CoC with anything on a list, but instead take a more holistic approach - that any proposed alternative must on balance improve the safety and environmental profile of the product.

**(b)(4) Safer Alternative** – It is not reasonable to suggest that any chemical that has a “safer alternative” should be considered a CoC. Any chemical that is added to a CoC list must demonstrate a realistic potential for exposure and adverse impacts to human health or the environment. For example, purified water might be considered to be “safer” than tap water from a municipal supply, by some extremely tiny margin. However, such justification does NOT prove that tap water should be considered a CoC. In addition, exposure under real-world conditions of use must be considered: if a chemical can potentially be replaced with another exhibiting lower hazard, but such substitution (due to reduced performance or other factors) results in a greater exposure, this may not be the desired outcome.

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

**Section 69503.1. Applicability** – The applicability section should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Per the comments above, reasonable and foreseeable exposure through normal use and abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. As discussed above, the U.S. Consumer Product Safety Commission (CPSC), in August 2009, once again endorsed the reasonable and foreseeable exposure criterion in regulation through the “Children’s Products Containing Lead; Interpretative Regulations on Inaccessible Component Parts” (16 CFR Part 1500).

**Section 69503.2. Priority Product Prioritization** – This section should recognize that reasonable and foreseeable exposure is the basis for a product being selected as a priority product. Per the comments above, reasonable and foreseeable exposure through normal use and abuse is an essential principle of proper chemicals regulation and is recognized nationally and around the world. Assembled products that only contain CoCs in inaccessible components - for which there is no reasonable and foreseeable exposure pathway - should not be prioritized under this section. Only accessible components of assembled products should be the focus of these regulations; since they are the only reasonable and foreseeable components with the potential for exposure. The principle of applying chemical regulations only to accessible components of assembled products has been validated by the U.S. Consumer Product Safety Commission (CPSC), the Maine Department of Environmental Protection (DEP), and Washington State DoE under substantially similar laws. CPSC regulations – 16 CFR, Part 1500.48 and 1500.49 – can provide guidance for DTSC regarding specific technical requirements for determining accessibility

Additionally, the Department does not have regulatory authority under this statute over workplace exposures to CoCs; especially if those exposures occur beyond California’s boundaries. Workplace exposures are the jurisdiction of U.S. OSHA and Cal OSHA. Thus these “manufacturing” exposure considerations should be removed from this Section.

#### **Section 69503.4. Priority Products List**

**(a)(2) Highly Durable Products** – As discussed above, “Highly Durable Products” should be changed to more closely reflect DTSC’s intent. After discussions with DTSC staff, it is clear that what was intended here is to denote a class of products which are “complex” rather than “highly durable” in order to limit the number of components on which a manufacturer might otherwise be required to perform simultaneous alternatives assessments. TIA remains concerned that the scope of products in this category is both arbitrary and unduly limited. Products with far fewer than 100 components may still be quite complex, and it is *arbitrary and capricious to summarily discriminate against children’s product makers* by excluding them from the (albeit limited) protections of this section when manufacturers of other product classes are not. We request that the Department look to redefine this section with terminology and standards which would minimize the burden for manufacturers of assembled products with 50 or more components, including children’s products manufacturers, who should not be put at a disadvantage compared to other manufacturers of assembled products which contain multiple components.

**Section 69503.5. Alternatives Analysis Threshold Exemption** – As outline above, the regulations do not provide a clear and predictable process for how AA threshold levels will be determined. Instead, the regulations provide that the Department may raise or lower a previously established AA threshold level, which creates future uncertainty. Additionally, the regulations do not address whether an unintentionally-added ingredient or a trace contaminant impact AA threshold. Once again, TIA urges DTSC to consider approaches consistent with Washington State and Maine – the regulations should set clear threshold levels and consider whether a chemical is intentionally-added or is a contaminant in setting the AA threshold level. We recommend the following structure:

- A. For a chemical that is an intentionally added chemical in an accessible component of a product, the practical quantification limit; or*
- B. For a Chemical of Concern Priority Product combination in which the chemical of concern is a contaminant present in an accessible component of a product, a concentration of 100 parts per million; or*
- C. Any concentration in a product, if that chemical occurs only in an inaccessible component or occurs in a product only as a contaminant, as long as the manufacturer had in place a manufacturing control program and exercised due diligence to minimize the presence of the contaminant in the component.*

**Section 69503.6 Alternatives Analysis Threshold Exemption Notifications** – As discussed above, the overly cumbersome process for filing an alternatives assessment threshold exemption is counter to the spirit and intent of this provision – which intends to acknowledge that there is no concern with such extremely small levels of a chemical in a product. The Department will be overwhelmed by unnecessary paperwork under this provision and consumers will be overwhelmed with information that may be confusing and misleading. The process requires the release of proprietary data, which would be public when the Department posts the AA threshold exemptions on their website, for products that are not a priority and pose no human health or environmental concerns.

TIA requests that the regulations strike the proposed exemption notification requirement and require only that a responsible entity notify the agency by letter within 60-days if it has a Priority Product that contains a Priority Chemical below the AA threshold level and allow such notifying entities to assert a right to confidentiality of the chemical identity if such information could plausibly allow competitors to ascertain confidential business information regarding raw materials, manufacturing processes, or other pertinent information. The Department could then request additional information if needed. This proposed change will allow the Department to carry out its mandate under the statute while minimizing administrative burdens for both reporting entities and DTSC.

**Article 5: Alternatives Assessment** – The alternatives assessment process is essential for developing safe and innovative children’s products. The fundamentals of the process are routinely executed as part of industry’s ongoing research and development and product improvement. The key to innovation, and better meeting consumer needs, expectations, and preferences, is the ability for manufacturers to draw on a variety of existing evaluation and decision making tools and approaches for developing products. Safety—protecting public health and the environment—is an inherent component of the product design process. Concepts that leverage existing practices in the product development paradigm should form the basis of a practical and meaningful regulatory framework for alternatives assessment.

Alternatives assessments may be undertaken by individual manufacturers, or by consortia representing an industry segment or an entire industry. Due consideration to safety, complexity (different factors are relevant to a specific chemical/product/use combination, and must be evaluated on a case-by-case basis), effectiveness, lifecycle thinking, consumer acceptance, cost to consumers, manufacturability, and informed decision-making (weighing trade-offs) will ensure a workable, practical, and meaningful Green Chemistry program in California. The most appropriate alternative for a particular product would be selected by the product manufacturer to ensure that it fits well within their unique business model.

A rational, structured and predictable alternatives assessment process is essential from a business perspective and TIA supports the Green Chemistry AA Coalition’s “Product development and improvement paradigm” as an appropriate framework.

Beyond these necessary factors for an Alternatives Assessment, TIA is concerned that as drafted DTSC would make the proprietary work and knowledge that a company must perform to complete an Alternative Assessment report publically available. We believe that by making a company’s Alternative Assessment report, and their conclusions, public (even if the report is redacted) would jeopardize a company’s ability to protect certain information as confidential business information (CBI).

**Article 8. Accreditation Bodies and Certified Assessors** – The use of certified AA assessors is an acceptable concept, but “certified” should not be read exclusively as “third-party”; the use of in-house assessors should be expressly permitted by regulation. Assessors should also not be required to be technically expert at all aspects of an AA, but should instead be expected to be capable of managing the AA process to be certain that all applicable parameters are considered.

In-house company experts (product development engineers and others within a company with product development responsibility) with 10 or more years of experience have the necessary knowledge, skills, and expertise to lead alternative assessment projects for product development and should not have to become certified assessors, or should be certified with minimal requirements based on their experience.

As stated above, the comments submitted by EU point to potential issues with setting up a highly unique accreditation and certification scheme that is not recognized beyond State boundaries. TIA shares these concerns, and recommends accreditation by an ISO 17021-accredited International Laboratory Accreditation Cooperation (ILAC) – Multilateral Recognition Arrangement (MLA) signatory be sufficient for the certification of assessors. Additionally, the process of certification should be such that certification is readily achievable by product development professionals with relevant experience and education. This approach would be in keeping with previous California precedent; when “Quality Engineer” was added to the state’s categories of engineering technology for which state licensing is available, already-practicing quality engineers with a minimum level of specified experience and/or education were “grandfathered” and granted a license without a licensing examination. Accreditation bodies should be held accountable for the quality of assessors (and of the assessors’ work products) that is being certified. DTSC should have the ability to challenge the Accreditation body.

#### **Article 10. Trade Secret Protection**

Since this Regulatory Program is groundbreaking in terms of its expansive scope and data submission requirements, TIA asserts that trade secrets must be strongly protected. The nature of the data required to be submitted - once a priority product and chemical concern combination have been designated, through alternatives assessment and regulatory response – is highly specific and unique. Therefore, unique provisions to protect trade secrets are warranted herein. It is a major concern to TIA that Confidential Business Information (CBI), may not fall within the definition of “trade secrets.” We recommend the following changes:

- A. Add to definition section, Confidential Business Information: *Any information in the custody of a business entity that the business entity reasonably expects to be preserved as confidential in order that the business may obtain or retain business advantage from its rights in the information.***
  
- B. Add a section to the Trade Secrets Provision: *In addition to trade secrets, a claim for Confidential Business Information will be reviewed by the Department to determine if disclosure of such information would cause substantial harmful effects to the claimant, including revealing capital and marketing costs, specialized technical expertise, unusual processes, or unique ingredients, or give competitors access to customers or information that may give them a competitive advantage. The claim shall include details of the substantial harmful effects to claimant, as well as a redacted form of the information.***

Additionally, the Department’s interpretation of statute that “chemical identity” is not considered a trade secret is problematic. Disclosure of a chemical’s identity often provides the ability for

competitors to determine trade secrets such as the raw materials being used in a product, or the process by which a product is made. Even if §25257(f) were interpreted as DTSC desires to mean that trade secret protection does not attach to hazard trait information, proposed §69510(f) still exceeds the scope of the statute. The proposed regulation does not merely ban trade secrecy protection for hazard trait submission information; it also eliminates trade secret protection for “any chemical identity information associated with a hazard trait submission.” However, §25257(f) does state that it does not apply to chemical identity information associated with a submission, just that it does not apply to “hazardous [sic] trait submissions.”

The problem with the Department’s interpretation of §25257(f) is that its interpretation fails to differentiate between “hazard traits,” which are specific hazards, such as corrosivity or ignitability, and “chemical identities,” which are a separate type of information different than hazard traits. It would be unreasonable to interpret §25257(f) as preventing persons from claiming trade secret protection for chemical identity information, because disclosure of a chemical’s identity often provides the ability for competitors to determine trade secrets such as the raw materials being used in a product, or the process by which a product is made. What §25257(f) speaks to are specific hazards, not chemical identity. A generic name for a specific chemical is acceptable as long as its specific hazard traits are disclosed. Section 69510(f) must therefore be eliminated, particularly its provision that does not allow companies to claim trade secrecy protection for chemical identity information.

**Conclusion:**

Product safety is a vital consideration for toy manufacturers. A core practice of our industry is to perform rigorous safety-based assessments for all products prior to the marketing of a product and take into consideration potential impacts on children. In addition to meeting stringent internal product safety requirements, toys currently comply with numerous federal and international environmental and safety regulations under a variety of laws and regulations.

TIA appreciates the hard work that has gone into the development of these Proposed Regulations and attempts to balance many stakeholder interests. TIA asserts that the current framework is critically flawed, and significant revisions are needed before this regulation can be considered workable.

Once again, TIA remains committed to working to ensure that these Regulations provide a workable solution to chemicals management issues in California and looks forward to continuing to work with you on these outstanding issues. Please feel free to contact TIA directly via Jennifer Gibbons at: [jgibbons@toyassociation.org](mailto:jgibbons@toyassociation.org) if you have any questions or concerns about these comments or would like to discuss in more detail.

Respectfully,



Jennifer Gibbons  
Director of State Government Affairs

TIA Comments  
Proposed Regulation for Safer Consumer Products  
October 11, 2012

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



**Tri-iso Inc.**

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October 2, 2012

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

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

Dear Ms. Von Burg:

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

Tri-iso is a U.S. West Coast distributor of specialty chemical raw materials. Tri-iso was founded in the late 1970's. Comprising a group of 25 employees and affiliates, Tri-iso offers extensive technical support and customer service for the products we represent. Our primary goal is to add innovative new products to our portfolio which meet our customer's performance, cost and environmental needs.

On a personal note, I take my personal, my families, my states and my nation's environmental needs very serious. I have put my money where my mouth is as I have driven a hybrid (electric and gas) vehicle for the last 3 years; I live off the grid and generate my households electrical needs via solar energy. My children and I are at the beach and usually in the water on a daily basis and we see the damage that is created from the lack of proper care for our environment and oceans. We regularly take part in organized and unorganized beach clean-ups.

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

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

However, there are many issues that we see RE: sections 69501-69510.1 (b)(2)(c)(d) as well as a few of the bullet points mentioned below.

- We remain highly concerned the current proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to



**Tri-iso Inc.**

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oversee this monumental Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).

- Most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what they must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products.
- It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we, in concurrence with GCA and its coalition members, strongly believe a comprehensive solution must be found rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we, in agreement with GCA, are firm in our belief that the prioritization and evaluation process must be based on exposure and **hazard**, and it must avoid duplication and conflicting regulatory requirements.
  - DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. ***This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemical in that group of 1200+ which should rightly be identified as Chemicals of Concern.*** No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.
  - GCA supports this two-step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals of "Chemicals Under Consideration." DTSC should next be intent on crafting a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. ***A discrete subgroup of***



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***these chemicals with expected exposures in California should be identified as Chemicals of Concern.***

- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.
- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

My last request, since you may consider Tri-iso and or me to be bias group, at the very least please give serious consideration to the recommendations made by The EU's Giuseppe Casella via email on Sept 11<sup>th</sup> titled G/TBT/NUSA/727. I believe we can consider Mr. Casella to be a neutral third party RE: DTSC.

We appreciate your consideration of our concerns. For further information or questions, please contact Jason Scott at 909/626-4855.

Sincerely,

A handwritten signature in black ink, appearing to read "Jason Scott", is placed on a light green rectangular background.

Jason Scott  
President/CEO

CC: The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Nancy McFadden, Cabinet Secretary, Office of the Governor  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor  
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October 9, 2012

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

Re: Green Chemistry Proposed Safer Consumer Products Regulations

Dear Ms. Von Burg:

On behalf of Tri-TAC, thank you for the opportunity to comment on the Proposed Safer Consumer Products Regulations (proposed regulations). We commend you and the DTSC staff for their systematic, science-based efforts to develop a robust process to improve product safety.

Tri-TAC is jointly sponsored by the California Water Environment Association, the League of California Cities, and the California Association of Sanitation Agencies. The constituency base for Tri-TAC collects, treats and reclaims more than 2 billion gallons of wastewater each day and serves most of the sewer population of California. Wastewater agencies must meet increasingly strict regulatory standards to protect our water resources for a broad array of beneficial uses. We take our responsibilities for safeguarding receiving waters seriously and are very concerned about discharges of certain chemicals into wastewater systems. The growing tide of unregulated chemicals has the potential to compromise effluent quality, biosolids management options, and compliance with National Pollution Discharge Elimination System (NPDES) permit requirements.

### **Support for Proposed Regulations**

Tri-TAC generally supports the concept of green chemistry and these proposed regulations, which have a solid scientific foundation and practical framework. We believe that in time, these regulations will help reduce harmful chemicals in consumer products and thereby assist wastewater treatment agencies in protecting receiving waters. In particular, we appreciate DTSC's efforts to include consideration of adverse impacts to wastewater treatment processes, water quality and aquatic life.

While Tri-TAC supports the proposed regulations and urges DTSC to move forward with them, we also have some suggestions for improvement, which are detailed below, that would strengthen the proposed regulations and have a beneficial impact on water quality.

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### **Incorporate Water Boards' Highest Priority Water Pollutants – 303(d) List**

Tri-TAC is pleased that the Proposed Regulations define “adverse water quality impacts” to include introduction or increases in pollutants that impair water bodies listed under section 303(d) of the federal Clean Water Act (p. 7, line 6). However, in the section “Chemicals of Concern Identification,” only pollutants listed under section 303(c) of the Clean Water Act are included (p. 22, line 35). A different list, developed by the Water Boards every few years under Section 303(d) of the Clean Water Act, lays out the state’s priority water pollution problems. This is the list of California’s most important water pollution problems. The 303(d) list meets all of DTSC’s stated criteria for inclusion among the lists of chemicals of concern and will help ensure that the most relevant pollutants from a water quality standpoint are considered as chemicals of concern are selected. We request that DTSC include 303(d) pollutants in Chemicals of Concern Identification.

While there is significant overlap between pollutants in section 303(c) and pollutants that have resulted in 303(d) impairments, there are some important differences in how these lists are developed. Water bodies may be deemed impaired under section 303(d) for virtually any pollutant, not just those listed under 303(c). The section 303(c) pollutant list does not change frequently and does not necessarily reflect pollutants affecting California waters. Including both 303(c) pollutants and the 303(d) pollutants in the “Chemicals of Concern Identification” will ensure that the highest priority water pollution problems in the state are addressed.

### **Incorporate High Priority Environmental Pollutants in Initial Priority Products List**

Tri-TAC understands that the proposed regulations must prioritize the vast number of consumer products; however, we are concerned that only products linked to human health concerns will be included in the initial Priority Products List. As currently proposed, the regulations do not allow DTSC to prioritize products containing chemicals that do not impact human health but may have environmental impacts. There are products, like copper-containing vehicle brake pads, that do not directly adversely impact human health, but may have significant impacts on water quality and the environment. We urge DTSC to consider incorporating the 303(c) and 303(d) pollutants into §69503.3. Possible language may be added as follows to p. 29, line 12:

- 12 (3) The chemical is identified as a priority toxic pollutant for California under section 303(c) of the federal Clean Water Act or is a pollutant that has been identified as a cause of impairment of one or more water bodies in California under Section 303(d) of the federal Clean Water Act.

### **Increase Transparency**

Alternatives Assessments. While we understand that DTSC wants to expedite the Alternatives Assessment (AA) process, Tri-TAC believes the proposed regulations should include a formal comment period on preliminary AAs and any revisions to work plans. A formal comment period provides greater transparency, ensures higher quality AAs, and leads to better results since stakeholders may provide insights that may be

overlooked by both certified assessors and DTSC staff. In addition, a formal comment period will provide necessary transparency given that Certified Alternatives Assessors may be employees of the same companies required to conduct an AA.

Invite Public Comment on Product Stewardship Plans. Tri-TAC believes that proposed Product Stewardship Plans for end-of-life management of products should be posted to the DTSC website and DTSC should invite public comment prior to approval of the plans.

Publish All Comments & Correspondence on Website. We also urge DTSC to incorporate language into the regulations (in §69501.5) that requires all notices, public comments, and correspondence with stakeholders to be published on the DTSC website.

### **Consider Costs Incurred by Other Types of Entities**

Wastewater agencies may be heavily impacted by chemicals in consumer products. Consumer products may contain chemicals in quantities that would lead to exceedances of effluent limitations at POTWs and/or water quality objectives in the State's waters. For example, if a chemical enters a municipal wastewater treatment plant in sufficient quantities, it is possible it could harm the crucial microorganisms used to treat wastewater, causing "process interference," or a plant "upset" where wastewater is no longer able to be treated properly before discharge. Process interference and upsets can result in costly NPDES permit violations. In addition, when surface water bodies become impaired by pollutants, wastewater agencies may be subject to additional requirements established as part of Total Maximum Daily Loads (TMDLs). The cost to wastewater facilities and other dischargers to comply with effluent limits and TMDLs can be millions of dollars. In some cases, treatment plant upgrades may be necessary to comply with TMDLs, at enormous cost to the public served by the treatment facility.

To address this, Tri-TAC encourages DTSC to make two changes:

- (1) add language to the Regulatory Response Selection Principles in §69506 (p.52, lines 17-26) so that costs and other burdens (§69506 (a) (4)) incurred by wastewater agencies are considered when selecting a regulatory response.
- (2) add language to provide explicit direction for DTSC to consider these costs as one of the product prioritization factors (§69503.2).

### **Incorporate Exposure Pathways Information in Preliminary Alternatives Assessments**

Tri-TAC appreciates that the proposed regulations require an assessment of exposure pathways from a Chemical of Concern in a Priority Product. However, we believe that the responsible entity should provide this information in the First Stage of the AA, rather than in the Second Stage. Early identification of exposure pathways is important so that any inadvertent omissions or inaccuracies can be addressed at the beginning of the AA process. In our experience with pesticide regulatory processes, certain exposure pathways are often inadvertently overlooked by manufacturers and regulatory entities.

If DTSC incorporates our comment above to invite public comment on Preliminary AAs, then any omitted exposure pathways can be identified by interested stakeholders.

**Consider Other “Unique Burdens”**

We urge DTSC to consider other “unique burdens” in its regulatory responses, and propose modification of §69506 (p.52, lines 24-25) as follows:

- (4) Any unique or additional burdens that would be imposed by the regulatory response upon sensitive subpopulations, environmentally sensitive habitats, endangered and threatened species listed by the California Department of Fish and Game, and environments in California that have been listed as impaired by the State or any federal regulatory agency.

Once again, Tri-TAC would like to commend DTSC’s efforts in developing these proposed regulations. With our suggested changes, we believe these regulations will help prevent pollution at the source and will better enable municipal wastewater agencies to meet their obligations to protect water quality and human health. Timely and robust implementation of these regulations is critical – without it, we expect that water quality problems that can only be solved by product reformulation will continue to require legislative solutions on a case-by-case, product-by-product basis, which is inefficient and politicizes the issues. California needs strong Safer Consumer Products Regulations that address problematic hazardous chemicals in consumer products, and that promote the creation and use of non-hazardous alternatives.

Thank you for your consideration of our comments. We look forward to participating in the process of advancing green chemistry and safer consumer products in California.

Sincerely,



Jacqueline Kepke, P.E.  
Tri-TAC Vice-Chair

October 10, 2012

**Via Email (draphael@dtsc.ca.gov)  
and Via Federal Express**

Ms. Debbie Raphael  
Director  
California Department of Toxic Substances Control  
1001 "I" Street  
Sacramento, California 95812

**Re: Comments of the Truck and Engine Manufacturers Association  
on the DTSC's Proposed Safer Consumer Product Regulations**

Dear Ms. Raphael:

Through this correspondence, the Truck and Engine Manufacturer's Association ("EMA") is submitting its initial comments regarding the proposed Safer Consumer Products Regulations ("Regulations") that the Department of Toxic Substances Control ("DTSC") released for public review and comment on July 27, 2012. EMA appreciates the opportunity to submit these comments, and we look forward to working with DTSC staff to ensure that the DTSC adopts Regulations that are lawful, feasible and cost-effective. As it stands now, the proposed Regulations do not satisfy those necessary criteria.

EMA is the trade association that represents the world's leading manufacturers of commercial engines, equipment and vehicles, other than passenger cars and airplanes. The products manufactured by EMA's members cover the full spectrum of engine and vehicle applications that power our national economy, and include non-hand-held lawn and garden equipment; heavy-duty construction equipment, such as bulldozers, earth-movers and cranes; agricultural machinery such as combines, tractors and sprayers; locomotive and marine engine power systems; on-highway trucks, buses and delivery vans; and stationary engines, including generators, drilling rigs, pumps, and emergency backup power systems. All of those products and more could be deemed to be consumer products - - more specifically, "highly durable products" - - under the draft Regulations sweeping definitions, and so could fall under the four-step program that DTSC has proposed to promote the development and utilization of safer consumer products. EMA regularly represents its members' interests in responding to federal and state regulatory initiatives that impact the engine and vehicle industry, and so has a direct interest in the Regulations at issue.

EMA supports the general intent of the underlying green chemistry statutes (AB 1789 and SB 509), which is to reduce the potential adverse health impacts from consumer products based on a transparent, easy-to-use and cost-effective regulatory process that does not conflict with, supercede or duplicate the regulatory programs of any other state, federal or international

agencies. EMA also acknowledges that such a cost-effective and easy-to-use green chemistry program might be implementable in the context of relatively simple consumer products, such as nail polish, children's toys or fireworks. However, that is simply not the case in the context of the very complex highly durable goods that are manufactured and assembled by EMA's members. To the contrary, and as detailed below, the proposed Regulations are fundamentally unworkable and infeasible in that context.

EMA is a member of the Complex Durable Goods Coalition ("Coalition") and fully endorses and incorporates by reference the comments that the Coalition is submitting. EMA's separate comments will highlight the additional issues and concerns that stem from the fact that the engine, vehicle and power equipment industries already are heavily regulated by federal and state agencies to ensure state-of-the-art emissions control and safety. Thus, the proposed Regulations are likely to create unlawful duplication and conflict with existing comprehensive regulatory programs. DTSC must address this threshold issue through appropriate exemptions and "off-ramps" before finalizing the proposed Regulations. EMA's comments also will discuss the inherently unworkable nature of the Regulations, which, in the context of the complex products manufactured and assembled by EMA's members, impose obligations relating to the redesign and remanufacture of product components on entities that do not design or manufacture those components.

The net result, as set forth below, is the clear conclusion that the proposed Regulations are fundamentally ill-suited to the types of products manufactured by EMA's members - - products that are comprised of thousands of components designed and formulated by a global network of independent component manufacturers, and already subject to comprehensive health and safety regulations. Accordingly, and consistent with the request that the Alliance of Automobile Manufacturers and the Global Automakers submitted on October 8, 2012, the definition of "consumer products" should be revised to exclude the commercial vehicles, engines and equipment manufactured by EMA's members.

### **The Proposed Regulations Will Unlawfully Conflict With Existing Regulatory Programs**

As an initial matter, the Regulations are likely to create unlawful conflicts with other existing regulatory programs. More specifically, with respect to the emissions of air pollutants, including greenhouse gases, engines, vehicles and equipment already are subject to comprehensive and technology-forcing emission standards and other emission-control requirements adopted by the U.S. Environmental Protection Agency ("EPA") under the federal Clean Air Act (42 U.S.C. §§7401, et seq.), and by the California Air Resources Board ("CARB") under the California Clean Air Act (Health & Safety Code §§39000, et seq.). Those standards and other requirements already are at the limit of what is technologically feasible to reduce emissions to near-zero levels, and are elements of an integrated nationwide program that ensures cutting-edge emission controls, while also ensuring that each of the fifty States do not enact separate regulatory programs that could easily frustrate the certification and sale of products that are specifically designed to move in and quite literally drive interstate commerce.

Of particular note and significance in this regard are the express preemption provisions of the federal Clean Air Act. Those provisions prohibit every state and political subdivision thereof, including the DTSC, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions from new on-highway vehicles and engines, and from new and non-new nonroad vehicles and engines. (See 42 U.S.C. §§7543.) The only possible exemption from that blanket preemption is provided to the State of California, acting exclusively through CARB. DTSC is afforded no such exemption from federal preemption, however, and so has no authority to adopt any requirements relating to the control of emissions of any air pollutants - - including toxic air contaminants, Proposition 65 substances, greenhouse gases, or other pollutants - - from any mobile sources.

In recognition of the force and scope of federal preemption, the proposed Regulations need to make clear that any engine, vehicle or piece of equipment that is subject to regulation by EPA under the federal Clean Air Act is excluded from the definition of covered “consumer product.” Otherwise, the Regulations will be subject to immediate challenge and invalidation upon their adoption.

The underlying California statutes make this clear as well. Specifically, Health and Safety Code, Section 25257.1 expressly provides that:

- (b) This [green chemistry] article does not authorize the department to supercede the regulatory authority of any other department or agency.
- (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.

Simply stated, DTSC is precluded from the outset from adopting any regulation or other requirement relating to the control of emissions from any on-highway or nonroad mobile source. That preclusion is absolute. It is not subject to DTSC’s independent assessment or consideration in the context of designating priority products or regulatory responses. Accordingly, the Regulations must be revised to state unequivocally that the DTSC shall not include in the definition of consumer products any products that are subject to the protections of federal preemption. Otherwise, the Regulations will serve only to foster and engender uncertainty and potential litigation as opposed to consumer safety.

The Regulations are poised to undermine and conflict with other comprehensive health and safety programs as well. For example, in the case of on-highway vehicles, the U.S. Department of Transportation’s (“DOT”) National Highway Traffic Safety Administration (“NHTSA”) prescribes numerous safety standards and requirements. Those Federal Motor Vehicle Safety Standards regulate the design and performance of almost all the major components of motor vehicles, including, but not limited to, brakes, accelerators, lights, tires, steering systems, glass, mirrors, windshield wipers, hoses, controls, seats, seat belts, roof panels, stability control systems, head restraints, impact protection systems, energy absorption systems,

locks, fuel systems, windshields, and interior materials. See, e.g., 49 CFR §§ 571.101, et seq. Additionally, the U.S. DOT's Federal Motor Carrier Safety Administration ("FMCSA") has its own set of comprehensive safety regulations that provide another layer of regulatory control over commercial motor vehicles, primarily affecting their brakes, lights and fuel tanks.

Accordingly, to the extent that the DTSC were to designate almost any vehicle component as a priority product, it would almost certainly create ripple effects that would spill over into the regulatory purview of NHTSA and FMCSA. Similarly, any DTSC-mandated reformulation of vehicle components would almost certainly require parallel regulatory approval processes by NHTSA and FMCSA, which processes could ultimately result in the rejection of proposed alternative component designs. The same holds true with respect to other engine-powered equipment, such as lawnmowers and construction equipment, the design and safety of which is regulated by the Consumer Product Safety Commission ("CPSC"), the Occupational Safety and Health Administration ("OSHA"), and other federal and state agencies.

From the foregoing, it is clear that the DTSC's proposed regulation of the components of highly durable goods - - specifically engines, vehicles and engine-powered equipment - - will almost certainly interfere or conflict with other pre-existing regulatory programs relating to the design, manufacture and assembly of those components. That, in turn, will result in the type of duplicative and conflicting regulations that the underlying California statute expressly prohibits. See Health and Safety Code § 25257.1. The net result is that DTSC should not endeavor to regulate those highly durable goods that are already subject to comprehensive health and safety regulations.

**The Proposed Regulations Should Apply To Component Manufacturers,  
Not Assemblers Of Complex Highly Durable Products**

The conclusion that the DTSC's proposed Regulations should not apply to currently regulated complex products is buttressed by the fact that the Regulations are fundamentally illogical when applied to the components of the highly durable goods manufactured by EMA's members. The Regulations aim to impose mandates for the redesign and remanufacture of components on entities that are not in the business of designing or manufacturing components. That is not only inherently illogical and unreasonable, but unworkable as well.

Engine, vehicle and equipment manufacturers are principally assemblers of the myriad component parts that are designed and manufactured by others. Thus, EMA's members assemble literally thousands of component parts that are manufactured by hundreds of suppliers. Moreover, those hundreds of suppliers are spread out around the world and engage in a world-wide supply and distribution business. They manufacture components that go into engines, vehicles and equipment that are sold and distributed throughout the world. As a result, the structure and dynamics of the engine and equipment industry cannot accommodate unique component design requirements solely for the California market. It is a global supply chain, not one that can be reconfigured exclusively for the State of California. Consequently, in order for components to be effectively and efficiently redesigned and remanufactured in this industry,

those redesigns must be implemented on an industry-wide and world-wide basis. DTSC is not in a position to lead or coordinate that type of global component redesign process for the types of highly complex products at issue.

Just as important, engine, vehicle and equipment manufacturers are not the entities that can implement component redesigns on an industry-wide basis. That is something only the components manufacturers can do. Component manufacturers have the expertise and the actual access to component chemical suppliers that is necessary to implement alternative component designs and formulations in a feasible and potentially cost-effective manner. Manufacturers - - component assemblers at the tail-end of the supply chain - - do not. Thus, the DTSC's regulations are directed at the wrong entities in the supply chain. Stated differently, the focus of the proposed regulatory scheme is upside-down. It seeks to impose mandates that need to be implemented at the beginning of the manufacturing process (the design and fabrication of component parts) by regulating the entity that is situated at the very end of the manufacturing process (the assembler of the components made by others). That creates an inherently impractical and unworkable situation.

Two simple examples can illustrate the illogical and unworkable nature of what the DTSC is proposing for the manufacturers of complex highly durable goods. In the first example, assume that the DTSC seeks to mandate the reformulation of the vinyl that is used in vehicle and equipment seat covers. Vehicle and equipment seats are actually complex systems that are regulated by NHTSA (and in some instances by OSHA or even the CPSC) to ensure crash-worthiness, suitable integration with seat belt systems, lack of flammability, ergonomics, durability and other factors. Moreover, a seat assembly is comprised of hundreds of components made by scores of component suppliers. The complete seat assemblies are typically installed in multiple vehicle and equipment types that are sold and distributed on a world-wide basis.

Accordingly, if seat covering material needed to be redesigned to meet a DTSC mandate, that directive would have to flow all the way up to the global supply chain to the actual seat material maker and its vinyl supplier. Those entities would have to explore alternative formulations and engage in prototype testing. Any new material that emerged from that process would then have to be integrated into the multi-step seat assembly process, so that the new seats could flow back down the global supply chain to vehicle and equipment assemblers. At that point, the integrated seat assembly system would be subject to NHTSA's (and potentially others') review and approval, which could result in additional modifications that would have to flow back up and down the global supply chain all over again. One unavoidable consequence of this tortured process is that in order for the redesign to be commercially viable, it would have to be implemented on a world-wide basis, which would bring even more players and other jurisdictions' regulations (including, specifically, the EU's "REACH" program) into the mix. All of this would create unworkable conflicts, costs and complexities.

This entire process would take many many years, and would involve many many entities outside the control of the vehicle assembler. Indeed, the vehicle assembler might be one of the entities with the least direct control over the entire process.

As a second example, assume that the DTSC seeks to mandate the reformulation of the polymers used in engine piston rings. Piston rings are components of piston systems that are integral to engine performance and durability. Piston rings create the necessary seal between the piston and the piston lining, which provides engine power while also preventing leaks of fuel and lube oils. Piston rings must maintain their structural integrity under extreme heat and very harsh operating conditions, including hundreds of piston strokes per minute over hundreds of thousands of miles of operation.

As in the case of seat covers, the hypothetical DTSC redesign mandate for piston rings would have to flow up the component supply chain to the piston manufacturer and then to its component part suppliers and ultimately to the piston ring maker and its polymer supplier. Those entities would have to try to reformulate and prototype test new piston ring materials that would then have to be integrated into new piston assemblies that would flow back down the global supply chain, ultimately to the engine builder. At that point, since piston rings can have direct impacts on engine emissions, the engine manufacturer would have to engage in extensive engine emissions and durability testing, and would need to obtain proper authorizations from EPA and CARB. Any failed emissions testing could result in the whole process returning to square one. And, due to the time and expense of the redesign process, any new piston ring that emerged would need to be integrated into a wide range of engine applications on a world-wide basis, which again would bring more jurisdictions and more confirmatory testing into play.

The engine manufacturer would not be the principal actor in this process and would not have direct control over the ultimate reformation of the piston ring materials. And, yet, the engine manufacturer would be the “responsible party” under the DTSC’s proposed regulatory regime. Once again, that is illogical and upside-down.

These two simple examples reveal the unworkable nature of what DTSC has proposed in the context of complex highly durable goods. Component manufacturers, not component assemblers, should be the regulated entity in the context of complex highly durable goods. As they currently stand, the proposed Regulations fail to account for the inherent lack of control that product assemblers have over the chemical content of product components. The DTSC Regulations also fail to account for the fact that any mandated component reformulations will, in reality, need to be researched and implemented on an industry-wide and, thus, world-wide basis. Individual manufacturers cannot possibly afford the time and cost of requiring redesigned components solely for their own products and solely for California. To the contrary, components for the type of highly complex goods at issues (engines, vehicles and equipment) would need to be redesigned and reformulated on an industry-wide (more likely, world-wide) basis. But the proposed Regulations fail to account for this. This is evidenced, at least in part, by the fact that the DTSC Regulations fail to mention let alone provide for the type of clear-cut antitrust exemption that would be needed to enable the industry-wide collaboration that would have to be undertaken to respond to the DTSC’s requirements, just as is provided under the National Cooperative Research and Production Act. See 15 U.S.C. §§ 4301-4306.

In sum, the proposed Regulations are unworkable and directed at the wrong entity in the context of the products manufactured by EMA’s members.

**The Proposed Logistics For Implementing  
The Regulations Are Unreasonable And Unworkable**

Turning to the logistics by which DTSC proposes to implement its four-step program, fundamental revisions are required to those aspects of the Regulations as well. Under the proposed Regulations, engines, vehicles and equipment would be included within the DTSC's proposed definition of "highly durable products." That means that the DTSC, subject to the constraints imposed by federal preemption and the underlying California statutes discussed above, could attempt to regulate up to ten (10) separate components of any type of engine, vehicle or piece of engine-powered equipment that the DTSC designated as a "priority product." (See Regulations §69503.4 (a)(2)(B).) As discussed above, that potential outcome under the Regulations as currently drafted is untenable (and illogical) as it would impose wholly unacceptable and unreasonable burdens on the manufacturers of engines, vehicles and equipment. Accordingly, and at the very least, the scope and timeline of the DTSC's proposal need to be revised substantially to make the Regulations workable on even a theoretical basis.

Today's engines, vehicles and engine-powered equipment (hereinafter "engine/vehicle products") are highly complex machines that take multiple years to design, prototype test, and prepare for manufacture and assembly. Engine/vehicle products contain literally thousands of highly sophisticated component parts, including state-of-the-art electronic controls and hardware/software systems that are manufactured by suppliers from around the globe. The coordination and integration of those thousands of parts and suppliers is a logistical challenge that requires years of leadtime to orchestrate, manage and implement. Any disruption of those complex global logistics, such as through a regulatory mandate to redesign and remanufacture up to ten (10) component parts at a time, will cause a cascading chain reaction (as described above) that will upset the delicate balance that goes into the scoping, procurement and assembly of the thousands of components that comprise engine/vehicle products. That, in turn, could result in products essential to California's economy either not being available, or being available at significantly greater cost.

The manner in which the Regulations propose to intrude into global manufacturing processes and logistics fails to account for the complexity, scope and cost of what is at stake. That intrusion is rendered even more unreasonable through the Regulations mandate that only "certified assessors" will be allowed to prepare the requisite alternative analyses. Mandating the involvement of those types of third parties into the global logistics that pertain to the products manufactured by EMA's members would only serve to add additional years of delay and layers of cost to a process that would already be destined to collapse under its own weight.

Turning to the Regulations specific provisions, the DTSC's current proposal to compel the redesign and remanufacture of up to ten (10) component parts at a time is unacceptable and unreasonable on its face. The time and resources required for such an undertaking on the schedule proposed by the DTSC would be overwhelming, and the manufacturers of engine/vehicle products (acting through their "certified assessors") would be called upon to fulfill completely unworkable mandates, involving far-flung component suppliers over which

manufacturers generally have no direct control. The leadtime and logistics that are inherent in the design and assembly of engine/vehicle products simply cannot accommodate the scope of regulatory intrusion that is envisioned under the Regulations as they now read.

At most, the Regulations should authorize the DTSC to specify up to three (3) - - not ten (10) - - components of engine/vehicle products for alternative analyses over any 4-year - - not 3-year - - time period. A minimum four-year period matches the period of regulatory lead time that is guaranteed to manufacturers under Section 202(a)(3)(C) of the federal Clean Air Act. (See 42 U.S.C. §7521(a)(3)(C).) That lead time period is necessary to ensure that manufacturers are not in a perpetual loop of redesigning their products to comply with shifting regulatory mandates. It also provides manufacturers with a sufficient period to try to manage the very significant redesign investments and costs that are necessarily involved in complying with the types of requirements spelled out in the Regulations. Shifting regulatory requirements - - in this instance, for the redesign and reformulation of component parts - - on a more frequent basis will engender unsustainable costs for the engine, vehicle and equipment industries and the related sectors of the economy. Stated differently, without the requisite minimum four-year lead time period, the unreasonable weight and cost of the resulting regulatory burdens on the manufacturers of complex durable goods will cause the collapse of the envisioned consumer products safety program.

Similarly, the timeline for the preparation of preliminary and final alternative analyses must be flexible enough to accommodate the time that manufacturers will need to work the necessary issues up and back down the impacted supply chain to assess and implement potential component redesigns in the context of globalized logistics. In that regard, requiring preliminary alternative analysis reports with 180 days of the listing of components as priority products is unworkable. Equally untenable is requiring final alternative analysis reports within 12-24 months of the DTSC's approval of the preliminary reports. The underlying global logistics for the design, manufacture and assembly of the components that comprise engine/vehicle products requires significantly more time than that. In the absence of a reasonable multi-year timeline, the DTSC's program will simply collapse under its own unsustainable weight.

### **Conclusion**

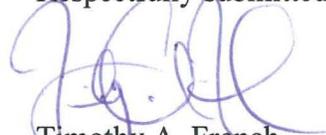
The proposed Regulations are preempted, inherently unworkable and fundamentally illogical in the context of the highly complex goods manufactured and assembled by EMA's members. Accordingly, in light of all the foregoing issues, and as stated at the outset, the definition of "consumer products" should be revised to exclude the commercial vehicles, engines and equipment that EMA's members produce and distribute on a world-wide basis.

As noted above, EMA's comments are supplemental to the comments that the Coalition has submitted, which comments EMA fully endorses and incorporates by reference. EMA looks forward to working with DTSC staff to resolve the important issues outlined herein and in the Coalition's submission to ensure that the final Regulations are lawful, feasible and cost-effective.

Ms. Debbie Raphael  
October 11, 2012  
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If you have any questions, or if you would like to discuss these comments, please do not hesitate to contact me.

Respectfully submitted,



Timothy A. French  
EMA General Counsel

cc: Matthew Rodriquez, Cal/EPA Secretary (via first class mail and email: [matthew.rodriquez@calepa.ca.gov](mailto:matthew.rodriquez@calepa.ca.gov))  
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October 10, 2012

Debbie Raphael  
Director  
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Dear Director Raphael,

Congratulations on the direction you have provided in moving the Safer Consumer Products Regulations forward and placing California in a position of national leadership in health and environmental protection and in industry innovation in green chemistry.

I am writing to highlight a number of concerns I have regarding the Regulations and the process of their implementation.

- A) **Timing:** Please make every effort to finalize the Regulations and implement them as quickly as possible. I see no compelling rationale for extending the time period for this process.
- B) **Listing Chemicals of Concern:** In examining the evidence, I see no compelling reason to constrain the number of Chemicals of Concern identified in the Regulations. The current number of about 1,200 reflects a minimum number of chemicals identified by credible scientific and governmental bodies around the world. The list catalogues this information, which to date has not been done in any systematic way. This provides a great service to businesses in California that are seeking to reduce their use of recognized toxic substances, and it reflects the practices of leading companies that are currently conducting business in California. It sends a reasonable signal to the market

that some chemicals can and should be recognized as toxic and should be avoided wherever possible.

- C) **Thresholds:** It is important that DTSC retain the authority to set the concentration level in a product for a Chemical of Concern at 0.01% (100 ppm) or lower, rather than allowing for a generalized level of 0.1% (1,000 ppm). It is not appropriate scientifically to set a single standard for all Chemicals of Concern as high as 0.1%, for example, as some substances are more potent toxicologically than others.
  
- D) **Alternative Assessments:** It will be important to streamline the AA process as much as possible. As written, I am concerned that the process could be bogged down, and companies will ask for extensions at each possible opportunity. In evaluating the AA process, my conclusion is that this would best be handled by DTSC in-house, which would avoid the need for accreditation bodies, certified assessors, and monitoring of the activities of these groups by DTSC. It would appear that this option would be less expensive for DTSC if the costs of establishing and monitoring accreditation bodies and assessors are considered. Additional steps are needed to allow public scrutiny of AA documents.
  
- E) **Non-chemical Alternatives:** On page 24, section 69502.2b(4), line 4. It is overly restrictive to allow only for safer chemical alternatives. I recommend that the regulations include the words “or safer engineering administrative approaches that produce a similar, safer function” after the words, “alternative chemical.”

I look forward to working with the Department in moving the regulations forward to the next step. Please let me know if there is any way I or my colleagues can be of assistance to you.

Best regards,



Michael P. Wilson  
Director

# Comments to July 2012 Safer Consumer Products Proposed Regulations, R-2011-02

Peter Sinsheimer Ph.D., MPH, Timothy Malloy, JD  
UCLA Sustainable Technology and Policy Program

10/9/12



These comments do not represent the opinion of the University of California or its Chancellors. Institutional affiliations are for identification purposes only and do not necessarily represent the views of the organization.

Section	Sub-section	Topic	Comment
Throughout		“Contribute to or cause”	Throughout the regulations, the terms “contribute to or cause” and “would contribute to or cause” to delineate impacts of concerns or concentrations of concern for chemicals. This imposes too high a standard of causation. The language should be modified to stress that the agency will consider the potential effects. In many cases, simply placing the word “may” in front of “contribute” will be enough. In others, slight rephrasing will be required to capture the concept.
69501.1(a)		Definitions	
		Exposure Pathway	Definition of exposure pathway needs to be developed since it is a significant concept for both prioritization of priority products and in the Alternatives Analysis. Section 69503.2(a)(1)(B) can be used as a basis for developing the definition.
	6	Adverse public health impacts	This term should also include public health-related “exposure potential hazard traits” identified in OEHHA’s regulations; namely, “lactational or transplacental transfer” and “particle size or fiber dimension.” It should also include physical chemical hazards. Since the term almost exclusively refers to hazard traits as listed in Chapter 54, the name should be changed to “Public Health Hazards.”
	59	Technically and economically feasible alternative	Statute lists these as separate criteria. Since they are fundamentally different they should be evaluated separately. “Feasibility” definitions should relate to whether the alternative is technically <i>possible</i> or economically <i>possible</i> . Definition of technical feasibility in the proposed regulation relates to the possibility of manufacturing the alternative and conforms to standard business definition of the term. Definition of economic feasibility is not related to the possibility of manufacturing the product and does not conform to the basic business definition of the term, and therefore is fundamentally flawed. Business definitions of economic feasibility do not describe the term in relation to whether “the manufacturer’s operating margin is not significantly reduced” as stated in the proposed regulation. An

Section	Sub-section	Topic	Comment
			<p>alternative that eliminates the use of CoCs in a targeted product may reduce the operating margin from 100% to 50%, but still generate sufficient return on the investment. Halving the operating margin would be considered “significant” reduction by most people yet most people would consider that a 50% margin economically feasible. The Cambridge Business English Dictionary (Cambridge University Press) defines the term as “the degree to which the economic advantages of something to be made, done, or achieved are greater than the economic costs.” This definition conforms to the definition developed by ECHA in their guidance for authorization of CoCs under REACH. (See ECHA, Guidance on the Preparation of an Application for Authorization, January 2011). ECHA defines the economic feasibility of an alternative as having a positive NPV (net present value) based in existing revenue for the product or possibly increased revenue if the cost for the alternative exceeds existing revenue. Such a definition is not only commensurable with the accepted definition of “economic feasibility” it coincides with the intent of the legislation.</p>
69501.3(a), (c)		Signing and certification requirements	<p>This provision significantly enhances the integrity of the program by ensuring that persons in positions of authority at the responsible entity engage in a meaningful way in the process.</p>
69501.4(d)		Safer Consumer Products Partner Recognition List: Voluntarily completed AA	<p>If an AA is completed by a qualified and certified 3<sup>rd</sup> party assessor and submitted to DTSC for a consumer product not listed as a priority product but contains one or more CoC and identifies a viable safer alternative, then the agency should be required consider the existence of that safer alternative in identifying Chemicals of Concern under Section 69502.2(b)(4) and prioritizing products under Section 69503.3(d)</p>
69502.2(b)	(3)	Availability of Information	<p>This section gives preference to a chemical that has more data regarding adverse impacts. An absolute presumption such as this could codify the view that absence of data is evidence of (relative) safety. In cases in which there is reason to believe that a chemical may exhibit a hazard trait, the agency should have discretion to view the absence of data as favoring identification. The language “all other factors being equal” does not sufficiently address this issue as it would still make the absence of data a “tie-breaker” in favor of exclusion as a</p>

Section	Sub-section	Topic	Comment
			CoC.
69502.2(b)	(4)	Safer alternatives	The regulation should identify the effect of identifying a safer alternative; does it weigh in favor of or against identification as a Chemical of Concern? In doing so, the availability of a safer alternative should be used as a factor <b>in favor</b> of identification. The goal of the statute is to advance innovation and adoption of safer alternatives. If a chemical exhibiting a hazard trait is currently in a product and a safer viable alternative exists, this is indication that the market is not itself advancing adoption of the safer viable alternative and that AB 1879 review and regulatory response may be called for. Of course, if the hazard is not significant or exposure is very low, other factors may lead to the conclusion that identification as a CoC is not appropriate.
69503.3	(d)	Process to Evaluate Products Using the Prioritization Factors: Safer Alternatives	If an AA is completed by a qualified and certified 3 <sup>rd</sup> party assessor and submitted to DTSC for a consumer product not listed as a priority product but contains one or more CoC and identifies a viable safer alternative, then the agency should be required consider the existence of that safer alternative in identifying Chemicals of Concern under Section 69502.2(b)(4) and prioritizing products under Section 69503.3(d)
69503.3	(f) (2)	Priority Product Work Plan – Subsequent work plans	A minimum number of new priority products should be required to be listed for each new work plan.
69503.5	(c)(3)	Alternatives Analysis Threshold Exemption	The provision contains no objective standard for setting the threshold. This is even more troubling given the implication in Section 69503.5(c)(1) that the threshold is meant to be driven by the level of unintended contaminants in the product and/or by the minimum detectable concentration. An exclusion from AA should be based primarily on health and environmental factors; i.e. a showing based upon reliable information that the potential for adverse impacts is extremely low—well below what would normally be set as an acceptable exposure level under conventional standard setting methods. Subsection (3) is insufficient to accomplish this goal because it would allow the agency to set a threshold at conventionally derived acceptable exposure limit. It is just this type of standard setting that AB 1879 was designed to avoid through comparative evaluation of products and alternatives.

Section	Sub-section	Topic	Comment
69505.2	(c)	Responsible entity's own AA process	Responsible entity's own AA process should not be in conflict with guidance provided in 69505.
69505.3	(b)(3)(C)	Step 3, Elimination of Alternatives Posing an Equal or Greater Adverse Impact	<p>Elimination of an alternative on the basis of only public health or environmental impacts is ill-advised. Those two types of impacts by definition do not include consideration of exposure. Thus, one could eliminate an alternative simply based on hazard traits when in fact the exposure profile is such that it is inherently safer than the Priority Product. Also, the comparison should look as aggregate net adverse impacts. This will ensure that the responsible party will assess the overall public health/environmental impacts rather than concentrating on one hazard trait.</p> <p>Any alternative identified by the responsible entity that poses an equal or great adverse impact as the Priority Product should be retained in the Stage One Alternatives Analysis and discussed in the Preliminary AA Report. DTSC should determine the validity of this claim and add all validated alternatives posing equal or greater adverse impacts as Priority Products. DTSC should take such findings into account in crafting regulatory responses for the Priority Product, and in prioritizing products going forward. Otherwise, such alternatives may find a market in California and may also put the regulated manufacturer at a market disadvantage whether or not a safer substitute is identified.</p>
69505.4	(a)(1)(A)	Alternatives Analysis: Second Stage	This sub-section discusses retaining only exposure pathway and life cycle factors that have (1) a demonstrable contribution to the adverse impact for either the Priority Product or one or more alternatives AND (2) demonstrable difference between two or more alternatives. Guidance needs to be developed to quantify demonstrable contributions and demonstrable differences. Does data need to be collected on exposure pathways and each lifecycle segment to demonstrate whether or not there is a contribution and whether or not there is a demonstrable difference? Can decision rules be developed to determine the probability of a demonstrable adverse impact and/or demonstrable difference in impacts between alternatives? For example, in implementing an alternatives analysis under REACH, ECHA has provided guidance on whether

Section	Sub-section	Topic	Comment
			exposure needs to be taken into account when evaluated the impact of alternatives to authorized chemicals. (See ECHA, Guidance on the Preparation of an Application for Authorization, January 2011)
69505.4	(a)(2)(B) 3.	Product function and performance	This sub-section calls for the determination of whether there exists a technically and economically feasible alternative. Since this section deals only with technical performance and not economic performance, this sub-section should focus on technical feasibility only. We recommend that technical and economic feasibility be separated into two definitions (see comment above).
69505.4	(a)(2)(C) 1.-8.	Economic impacts	This list of cost impacts is confusing and overlapping. For example, materials and resource consumption costs are clearly part of manufacturing costs. Business costs are listed along with government agency costs and public costs. How is a business cost defined? Are manufacturing costs part of business costs? Do waste and end-of-life management costs include costs incurred by manufacturer, end user, government? Each term here should be clearly defined.
69505.4	(b)(6)	Weighting	This section needs to state that DTSC will develop guidance on how to weight relevant criteria
69505.5(a)	(2)	Department Review of AA	The language should be modified to clarify that the Department has the authority to substantively review the AA Report. For example: "The responsible entity must include in both reports sufficient information for the Department to determine compliance with the substantive and administrative requirements of this article."
69505.6(a)	(1)	Department Review of AA	The language should be modified to clarify that the Department has the authority to substantively review the AA Report. For example: " Within sixty (60) days of receiving a Preliminary AA Report, the Department shall review the Preliminary AA Report for compliance with the substantive and administrative requirements of this article, including the demonstrations required under Section 69505.4(b). The Department shall issue a notice of its findings with either a notice of compliance or a notice of deficiency."  Similar changes would be required for Section 69505.6(a)(2)(B)
69505.6(a)	(2)(C)	Department Review of AA	Add a new subsection to clarify that the Department may modify the Preliminary AA in the event that the

Section	Sub-section	Topic	Comment
			responsible entity fails to comply with the notice of deficiency.
69505.6(b)	(1)	Department Review of AA	<p>The language should be modified to clarify that the Department has the authority to substantively review the Final AA Report. For example: “ Within sixty (60) days of receiving a Final AA Report, the Department shall review the Final AA Report for compliance with the substantive and administrative requirements of this article, including the demonstrations required under Section 69505.4(b). The Department shall issue a notice of its findings with either a notice of compliance or a notice of deficiency.”</p> <p>Similar changes would be required for Section 69505.6.(b)(3), and Section69505.6(b)(3)(B)</p>
69505.6(b)	(3)(C)	Department Review of AA	Add a new subsection to clarify that the Department may modify the Final AA Report in the event that the responsible entity fails to comply with the notice of deficiency.
69506		Regulatory Response Selection Principles	This is a good addition to the regulations, providing clear guidance in the selection of regulatory responses. It should also confirm that the Department is authorized to take a regulatory response on the basis of an approved AA, a disapproved AA or an AA developed by or modified by the Department.
69506.11	(b)(6)	Exemption from Regulatory Response	An exemption should not be available if the exemption is inconsistent with the principles established in Section 69506. For example, take the case of a federal or state regulation that addresses an adverse public health impact through engineering controls even though a safer alternative exists. The preference in Section 69506 for inherent protection should prevent issuance of an exemption in that case.



**Comments of Unifrax I LLC  
on  
Notice of Proposed Rulemaking  
Safer Consumer Product Alternatives**

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

**October 11, 2012**

**Introduction**

Unifrax I LLC, a manufacturer of Refractory Ceramic Fiber (RCF), offers the following comments on the July 2012 proposed regulations for Safer Consumer Product Alternatives, also known as the "green chemistry" regulations.

RCF is a high temperature insulation material that produces energy savings up to 40% or more in industrial furnaces in industries such as petrochemicals, metal forges and semiconductors, as well as other industries such as vehicle emission controls. In these times, it is particularly important to encourage use of such materials where they can be used safely. For over 20 years, RCFC and its members repeatedly have been commended for their dedication to product stewardship and workplace health protection. Since the late 1980's, RCFC and its member companies have developed and implemented a comprehensive Product Stewardship Program (PSP) to control potential workplace and other exposures to RCF. As discussed further below, the RCF PSP has been endorsed by OSHA, NIOSH and EPA at the federal level. The California Occupational Health Standards Board has commended the PSP as well.

The new proposal cuts back on several of the procedural protections provided in prior drafts:

- (1) The exemption for "bulk chemical products" not sold directly to retail consumers has been eliminated;
- (2) The exemption for exposure pathways regulated under other state or federal regulations has been eliminated, and this issue has been reduced to one of many general considerations in the priority product determination,
- (3) The definition of "feasibility" with respect to potential alternative products has been revised and narrowed to exclude certain external economic factors.

The final regulations should restore these protections as provided in the prior drafts. In addition, the final regulations and statement of reasons should clarify the following:

- (1) Existing regulation of a potential exposure pathway should be deemed adequate where additional regulation has been investigated and found to be unwarranted; and
- (3) Existing regulation should include product stewardship programs that have been determined by regulatory authorities to provide adequate protection.

These points are discussed below, following a summary of current RCF uses and potential exposure in California.

### **RCF Uses and Potential California Exposures**

RCF is a synthetic vitreous fiber first discovered in 1942 and commercialized in the 1960s. RCF is the smallest segment of the synthetic vitreous fiber industry, representing about 2% of total production, and is used primarily in industrial applications. Approximately 100 million pounds is produced annually in North America,

with between 5-6% sold into California (representing approximately \$9.4 million in sales). The total exposed population in the United States is approximately 26,000 workers, approximately 1,300 of which work in California end user plants.

RCF is an energy efficient insulation capable of very high temperature applications, up to 2800°F. RCF is an important product for furnaces, heaters, and reactors in the petroleum, petrochemical, chemical, fertilizer, steel, heat-treating, nonferrous metals, glass, ceramic, foundry, cement, and forging industries. Other uses are in fire protection, automotive catalytic converters, heat shields, air bags, aerospace, and defense applications. It is produced in a variety of forms, including bulk, blanket, modules, paper, felt, and textiles.

Globally, RCFs play an important energy efficient and environmentally friendly role by controlling high temperatures and reducing fossil fuel consumption. U.S. production of RCF is sold primarily into industrial furnace markets, saving an estimated 164 trillion BTUs annually, equivalent to 27.8 million barrels of oil, near \$1.4 billion at \$50/barrel, a huge impact on the US economy. As a superior energy efficient insulation product, RCF plays an important role for industry both in California's aggressive initiative under AB 32, as well as regional, national and international efforts, to reduce greenhouse gas emissions. For example, in a *single* 2,000 square foot batch (cycling) furnace, such as would be used in the metals processing or ceramic industries, RCF insulation would save \$200,000 to \$500,000 annually as compared to more traditional insulations, depending upon the fuel used for the furnace. In an environmental context the reduction in CO<sub>2</sub> emissions would range from approximately 1,100 to 1,600 metric

tons annually; this savings would be equivalent to removing from 230 to 315 cars from the highway.

RCFs are produced using a melt fiberization process, under highly controlled conditions, similar to processes for manufacturing other synthetic vitreous fibers (e.g., fiberglass and mineral wool). Primary fibers are produced in five plants in the United States and two in Mexico. Thus, the principal impact of the proposed PEL is on industries located in California that use RCF in critical applications. Those industries include:

➤ Petrochemical industry:

- Most furnaces have been designed to use RCF products because it is far lighter than other refractory products (for example, RCF weighs 8-10 pounds a cubic foot, while denser refractories can weigh between 65-150 pounds per cubic foot).
- If unable to use RCF in petrochemical furnaces, the impact would be very significant, particularly in terms of energy use since other refractories (with poorer insulation properties) require many more Btu's per hour because of the energy required to heat the furnace walls. Retrofit of a furnace to accommodate conventional refractories would virtually require a new furnace designed to accommodate heavy refractories.

➤ Forging industry

- Most furnaces are lined with RCF and use natural gas to heat to high temperatures.
- RCF is much lighter and has superior insulating properties. Furnaces can be cycled, and even idled; heating up for use takes as little as an hour and a half, while thermal shock is a real issue for other refractories thereby making cycling more difficult.
- If forced to use firebrick or other denser refractories, the cost of natural gas and refractories themselves in a cycling furnace would skyrocket.

➤ Semiconductor industry

- RCF is used in diffusion furnaces, where it supports the quartz tubes used to run gases such as argon through the furnace, to provide the appropriate thermal conductivity.

- RCF is also used in vestibule block at the end of the furnace; the vestibule blocks are made from vacuum formed RCF and are also circumferentially encapsulated in RCF blanket.
  - While the amount of RCF used in the semiconductor industry is relatively small compared to the amount used in the petrochemical and forging furnaces, the impact on the marketplace in California would be substantial. Without the ability to use RCF in diffusion furnaces, numerous companies in Silicon Valley would be required to re-engineer this process at substantial cost.
- Emission control industry
- RCF emission control products for diesel and other mobile source emissions play a vital role in providing the control devices essential for compliance with state and federal emission control regulations.

### **Bulk Chemical Products**

The prior draft regulations included a provision exempting the following products from preparation of alternatives assessments:

A bulk chemical that is placed into the stream of commerce in California and that meets the definition of a “consumer product”, as defined in Health and Safety Code section 28 25251, but that is not packaged for sale to, or end use by, a retail consumer.

Unifrax supported this provisions as consistent with the applicable legal requirements and the intent of the enabling legislation. However, it has been eliminated from the present proposal.

Unifrax urges DTSC to include this exemption in the final regulations. The program is intended to protect against adverse effects from consumer exposure to chemical products, including potential effects on sensitive subpopulations such as infants and children (Section 25252(a)). Bulk products, such as RCF shipped to CA for further processing, present no potential for such exposure provided other applicable regulations are satisfied. Further, as discussed below this program is not to duplicate or supersede other regulatory requirements. In case where exposure to bulk products is

limited to workplace settings, and the applicable workplace requirements are met, no further regulation under this program is permitted.

It appears that the exemption in the prior draft would only apply to the requirement that manufacturers of priority products must prepare an alternatives assessment. Accordingly, while it would not prevent a product from being listed as a priority product, if listing were to occur no alternatives assessment would be required. Unifrax supports this approach but urges DTSC to consider it at an earlier stage in the process where warranted. For example, if it is clear that a particular product is likely to be exempt from the alternatives analysis under this provision, it should not be listed as a priority product.

### **Existing Regulation**

Under the prior proposed regulations, a product could be exempted from the listing and subsequent regulatory processes if the Department determines that existing regulation is adequate throughout the life cycle of the product and there are no significant gaps in regulatory coverage. This exemption also has been deleted from the current proposal and replaced with a provision that makes existing regulation only one of many considerations in the priority process.

The proposed approach is not consistent with the governing statute. Section 25257.1 provides: "(b) This article does not authorize the department to supersede the regulatory authority of any other department or agency. (c) The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article." This language is clear: existing regulation cannot be superseded or duplicated. Thus, an

exemption is required for potential exposure pathways already regulated. Demoting this consideration to one of many in the priority process, which the Department presumably could overrule in some cases, is a violation of the statute. The prior exemption should be reinstated in the final rule.

The Department also should clarify that existing regulation of a potential exposure pathway is deemed adequate where additional regulation has been investigated by regulatory authorities and found to be unwarranted. With respect to RCF, such conclusions have been drawn by the federal authorities at EPA, OSHA and NIOSH, respectively.

#### EPA

The current regulatory focus on occupational RCF exposure is a direct result of an EPA investigation of RCF pursuant to the federal Toxic Substances Control Act (TSCA). In 1991, EPA initiated an accelerated review of RCF under TSCA Section 4(f). The Section 4(f) review could have resulted in a ban or other regulation of RCF pursuant to TSCA Sections 5 or 6, or referral of the issue to OSHA for regulation pursuant to TSCA Section 9. It could also have resulted in regulation of RCF as an "imminent hazard" pursuant to TSCA section 7.

Section 4(f) requires a 6-month expedited review. At the conclusion of the RCF review period, EPA determined that the available RCF studies were not a sufficient basis for determining whether RCF exposures pose significant or unreasonable risk. In view of this decision, EPA decided to continue its investigation of RCF data through negotiation of a consent agreement order under TSCA Section 4 to obtain additional exposure monitoring. The agency also decided to consider a "significant new use rule"

(SNUR) regulating new uses of RCF. No other regulatory action was proposed. The subsequent Federal Register notice of March 21, 1994, proposing the RCF SNUR, describes the results of the 4(f) review:

On November 21, 1991, the Agency concluded that, based on animal inhalation data submitted to the Agency under section 8(e) of TSCA, RCFs may present an unreasonable risk of cancer to human health. After conducting an accelerated review of RCF under section 4(f), EPA concluded there was not sufficient data available (particularly on exposure to and substitutes for RCF) to determine whether or not RCFs present an unreasonable risk. However, there was sufficient basis for human health concerns to initiate a regulatory investigation of RCFs to determine whether action under TSCA section 6 to control the use of RCFs was appropriate. The regulatory investigation of RCFs includes a thorough review of a recently completed multiple dose animal inhalation study, an update of the findings from an ongoing worker epidemiology study, an analysis of substitutes, and development of comprehensive exposure data. (EPA and three of the six domestic manufacturers of RCF have recently entered a consent agreement which provides for the collection of exposure monitoring data from the facilities of the participating companies and their customers.)

EPA has never adopted a final SNUR for RCF. Following the 4(f) review, the RCF industry signed a monitoring consent agreement with EPA that led to development of the current PSP and REG. The monitoring data and the studies of other potential exposure pathways, discussed further below, have led both the industry and regulators to focus on occupational exposures as the only potentially significant RCF exposure pathway. This in turn led to the current agreement with OSHA and NIOSH Criteria Document for RCF, also discussed further below. Over the years, the industry routinely has included EPA staff in PSP updates and has interacted extensively with EPA scientific staff reviewing and developing RCF health data and analyses pursuant to the agency's Integrated Risk Information System (IRIS). To date, these activities appear to

have convinced EPA staff that the conclusions of the 1991 review remain valid and that no further action is necessary.

In the early 1990s, EPA also proposed to list RCF as a hazardous substance for purposes of hazardous waste and Superfund regulation, as well as reporting under the Community Right to Know rules. The bases for the proposal were the listing of "fine mineral fibers" as a hazardous air pollutant in the Clean Air Act Amendments of 1990, and an early IRIS listing for RCF that described the scientific data available at the time. The proposed RCF listing was not finalized. The Clean Air Act listing does not apply because it is limited in the statute to "mineral fiber emissions from facilities manufacturing or processing glass, rock, or slag fibers (or other mineral derived fibers) of average diameter 1micrometer or less." The IRIS listing was not used because EPA had concluded in the 1991 TSCA 4(f) review that the same studies were not a sufficient basis for RCF risk assessment.

### OSHA

One of the basic findings of the RCF 4(f) review and subsequent exposure monitoring is that potential risk is confined to workplace exposures. In more recent years, this has led the industry to focus its efforts on interactions with OSHA staff. The two PSP programs that OSHA has endorsed, PSP 2002 and PSP-HTW, are the culmination of these efforts.

The OSHA letters endorsing the two PSP programs do not contain any findings that they are necessary to prevent significant workplace risks, but do acknowledge that they are effective methods for risk reduction. For example, the February 11, 2002 from OSHA head John Henshaw (at that time) states:

Although the success of PSP 2002 cannot be evaluated until the progress reports specified in the Program are reviewed, the actions that RCFC has committed to take help address the concerns that led to OSHA's identifying synthetic vitreous fibers (SVF), including RCF as a high priority for action... OSHA does not, at this time, consider RCF a regulatory priority.

The same letter goes on to state:

OSHA believes that the commitments RCFC has made in developing this Program form an important step towards further improving worker protection. The 0.5 fiber/cc exposure guideline recommended in the Program, the specific engineering controls and work practices detailed in the Program, and the recognition that respiratory protection is appropriate in certain operations will help reduce exposures of the workers who handle RCF products daily. . . .

By letter of May 23, 2007 from OSHA head Edwin Foulke, OSHA reaffirmed its commitment to the most recent update of the RCF PSP, PSP-HTW. The letter does not contain any finding that the PSP or the REG are necessary to prevent significant workplace risk, nor does it suggest that any more recent data are sufficient to cause reconsideration of this issue.

### NIOSH

NIOSH issued a Criteria Document for RCF (#2006-123) in 2006, after an extensive review of available literature and data both by NIOSH scientists and external experts. NIOSH initially considered adoption of an REL of 0.2 f/cc but ultimately elected to adopt 0.5 f/cc REL, consistent with OSHA and the industry's REG.

### Cal OSHA

In California, RCF is subject to two different occupational exposure limits. On the federal level and in all other states, the applicable standard is 0.5 fibers per cubic centimeter (f/cc). As discussed further below, 0.5 f/cc is the Recommend Exposure

Guideline (REG) in the industry's PSP, which has been endorsed by federal OSHA and NIOSH and can be enforced by OSHA.

In 2009, the California Occupational Safety and Health Standards Board adopted a state permissible exposure limit (PEL) for RCF of 0.2 f/cc. In adopting this PEL, the Board stated:

The Standards Board would like to note that it applauds the RCF industry's support of research on the potential hazards of RCF, and the product stewardship effort of RCF producers. The RCF industry has collected exposure data under a quality assurance project plan designed in conjunction with Federal EPA. These data have been shared with the Division as well as U.S. Department of Labor and other interested regulators. These data show that, with the help of RCF producers, users have achieved average TWA exposures well below the voluntary limit of 0.5 f/cc and in most circumstances at or below the proposed PEL of 0.2 f/cc. Therefore, in light of the totality of evidence cited by ACGIH and NIOSH on the potential for RCF to cause or contribute to respiratory disease, the Standards Board believes that a PEL for refractory ceramic fiber of 0.2 f/cc is feasible and necessary to protect workers.

The Standards Board appreciates the concerns raised by RCFC that, although measurements of airborne exposure to RCF for some operations have averaged below 0.2 fibers/cc, the variability of the results indicates that employers cannot assume that a single sample on any particular day will always indicate an 8-hour TWA exposure that does not exceed this level. These employers will have the option of supplementing engineering controls with respirator use or finding ways to improve engineering controls.<sup>1</sup>

Unifrax disagreed with the Board's decision and continues to believe that the 0.5 f/cc REG is the most appropriate standard for RCF exposure, as the federal authorities have recognized. Unifrax is committed to compliance with the Cal OSHA standard as the workplace standard in CA, and understands that the Cal OSHA standard will be the governing workplace standard under these regulations. However, in evaluating other

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<sup>1</sup> Occupational Safety and Health Standards Board, "Final Statement of Reasons, Airborne Contaminants," p. 30 (Public Hearing March 19, 2009). A detailed discussion of RCF issues can be found on pp. 28-52 of this document.

potential exposure pathways Unifrax believes that the 0.5 f/cc REG is the most appropriate standard. We believe this is fully consistent with the statutory directives to consider "worker safety and public health" and to "use, to the maximum extent feasible," information and standards developed by other public or private regulatory bodies.<sup>2</sup>

### **RCF Product Stewardship**

For purposes of these regulations, existing regulation should include product stewardship programs that have been determined by regulatory authorities to provide adequate protection. Again this is fully consistent with the statutory direction to place maximum reliance on the work of other public and private regulatory bodies.

The principal U.S. manufacturers of RCF began in-plant and customer monitoring of RCF exposures in the 1970s. A formal *product stewardship program* (PSP) was adopted in 1990, was incorporated in a consent order with EPA in 1993 and endorsed by OSHA as discussed above, first as PSP-2002 and then again in 2007 as PSP-HTW. The following is a summary of the elements of PSP-HTW.

Scope. The PSP applies to the manufacture, fabrication, furnace-lining installation and removal, and other settings where exposure to RCF may occur. RCF manufacturers are directly responsible for compliance at their own operations, and undertake the various activities described in the PSP to encourage customer compliance. The PSP grew in part from a voluntary Consent Agreement negotiated with EPA in the 1990s, which was the first such agreement ever to provide for monitoring at user operations. Subsequently, several user groups have formed trade associations to encourage PSP compliance. The Refractory Ceramic Fiber Coalition

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<sup>2</sup> Health and Safety Code Sections 25252(b)(2), 25252.5(b)(4).

(RCFC) maintains a website, [www.rcfc.net](http://www.rcfc.net), to provide updates information for its customers and the public.

Recommended exposure guideline. As discussed above, the PSP includes a recommended exposure guideline ("REG") of 0.5 f/cc, 8-hour time weighted average (TWA). The REG is based upon the data obtained pursuant to the PSP and EPA Consent Agreement, which indicates that it is generally feasible to maintain a workplace concentration of 0.5 f/cc with engineering controls in many RCF operations, and the RCFC philosophy that it is prudent to implement feasible and necessary workplace engineering controls.

The PSP is generally premised upon an intent to reduce RCF exposures to the lowest feasible level. The REG is a useful benchmark in this regard. Where it is feasible to reduce workplace concentrations to levels below 0.5 f/cc, the industry recognizes that it is prudent to do so and recommends continued efforts to maintain the lowest levels consistently achieved. As discussed above, to ensure that workplace concentrations below the REG of 0.5 f/cc are attained consistently, it is frequently necessary to maintain concentrations below that level. These aspects of the PSP were cited by OSHA as particularly important in its decision to support the PSP.

Control measures. The PSP obligates manufacturers to use product design, engineering controls, work practices, respiratory protection or a combination thereof to achieve, for each of its workers, exposure control consistent with the PSP provisions. While engineering controls are used where feasible and necessary, the industry may utilize other techniques to assure worker protection. In such cases, RCFC and its members strive to ensure that any changes to product properties do not lead to an

increased compliance burden on the part of users. Where workplace exposures are currently below the voluntary 0.5 f/cc, 8-hour TWA REG, RCFC and its member companies are committed to a continuing improvement program to reduce workplace exposure further. RCFC and its member companies also provide information to RCF product users regarding exposure control techniques and best practices. On a case-by-case basis, assistance or guidance is provided to end-users and they are encouraged to develop and implement effective exposure controls.

Work practices. The RCF manufacturers encourage employers and employees to follow proper handling guidelines for RCF. RCFC provides recommended work practice guidelines, in both video and written format. These work practices include recommendations for cost-effective engineering controls, proper respirator use, use of protective clothing and workplace handling guidelines.

Worker training. The RCF manufacturers provide health and safety training for their employees consistent with applicable OSHA requirements for Hazard Communication. We also provide health and safety training to end-users, consistent with targets established in the PSP. We participate in trade shows, conferences and other relevant events that provide suitable forums for communicating RCF-related health and safety information and guidance to end-users. We have developed a communications program designed to promote and advertise training seminars and other training opportunities.

Respirator use. RCFC and its member companies support OSHA's respiratory protection standards, which form the basis for RCFC's respiratory protection program. RCFC's training programs and materials incorporate all relevant requirements of

OSHA's respiratory protection standard. Appropriate respiratory protection is used when employee exposures are not "reliably" below industry guidelines (based upon task-specific information; preferably employer-specific data, but relevant data from other sources may also be used). We recommend the use of appropriate respiratory protection to end-users, in the circumstances where occupational exposures may exceed industry guidelines and effective engineering controls are not readily available. When workers use respirators, RCFC recommends the use of respirators certified by NIOSH under 42 CFR Part 84. RCFC, in consultation with the EPA, OSHA, NIOSH and other parties, reviews the program periodically and modifies it expeditiously where a change is appropriate.

Medical monitoring. RCF manufacturing companies maintain medical monitoring programs for workers producing RCF, consistent with acceptable surveillance practices and protocols. The medical monitoring program was designed by epidemiology researchers at the University of Cincinnati to investigate and identify any incidence of RCF-related health effects. In particular, the study employs chest X-rays and spirometry tests to identify potential instances of fibrosis, lung cancer or mesothelioma.

Product research. The PSP encourages research to develop new, improved RCF product forms. New RCF product research generally focuses on three key elements - dose, dimension and durability. To reduce the potential for worker exposure (i.e., reduce dose), various methods are being explored to contain RCF. RCFC members investigate options to alter the size distribution (i.e., dimension) of RCF to reduce the fraction in the respirable range (less than 3 microns in diameter) while maintaining key performance properties. In the past decade, great progress has been made, pursuant

to this program, in developing and marketing more soluble fiber products suitable for many RCF applications.

Waste minimization and disposal. Pursuant to the PSP, RCF manufacturers continue to study, recommend and implement waste minimization programs designed to reduce quantities of waste produced per unit of product and to increase recycling rates where practicable and effective. RCFC also continues to study and recommend after-service and solid waste handling procedures of RCFC members and their customers and to recommend appropriate handling procedures for disposal of friable RCF wastes.

Environmental responsibility. The PSP obligates RCFC members to design and/or modify their processes so as to minimize consumption of natural resources and energy and to eliminate, to the extent feasible, the generation of waste materials and releases to the environment. In so doing, the companies continue to focus on source reduction as the preferred approach to waste management, followed by internal recycle/recovery. Treatment or disposal is employed as a last resort. We strive to design and/or modify products and packaging in a manner that minimizes environmental impact throughout the product's life cycle. This includes ultimate disposal in a manner that assures that all applicable regulatory requirements are met.

Reporting. The RCF manufacturers generate annual reports to document PSP progress. We submit copies of the annual PSP reports to OSHA, NIOSH, EPA, and various user associations. These reports provide exposure monitoring results and information on program performance, including progress on program deliverables and specific measures of program performance. The reports also provide the latest available information from the RCFC epidemiological study and medical surveillance

program. In addition, RCFC keeps OSHA, NIOSH and EPA officials informed of significant developments in the scientific and medical assessment of RCF products through periodic informal meetings.

Exposure monitoring. Another key component of the PSP for RCF is exposure monitoring. Results of this program have been published extensively in the peer-reviewed literature. The most recent publication from the journal *Inhalation Toxicology* was authored jointly with personnel from OSHA and NIOSH.

RCF manufacturers monitor fiber concentrations in their respective plants. And, time trends show that exposures have been reduced in these facilities. But the program has a much broader scope; personnel from RCFC member companies also monitor their customers. As a result the industry has a substantial body (now 18 years and well over 17,000 samples) of monitoring data, indicating consistently that the industry has made substantial progress in reducing weighted average exposures at customer facilities.

Health studies. Various animal studies commissioned by the RCF manufacturers in the 1980s appeared to confirm that RCF was an animal carcinogen under certain test conditions, e.g., the "maximum tolerated dose" (MTD) of approximately 200 f/cc inhaled directly into the lungs. A later review of the MTD pathology indicated that the animals' lungs were "overloaded" because of large quantities of non-fibrous particles, and that this overload condition was likely responsible for the disease observed. In fact, evaluation of the aerosol samples used confirmed the presence of significant quantities of particulate matter. In a subsequent multi-dose animal inhalation study at 25 f/cc, 75

f/cc, and 115 f/cc; a *no observed effect level* (NOEL) was found at 25 f/cc. This level is 50 times the RCFC recommended REG of 0.5 f/cc for humans.

The RCF manufacturers also have engaged the University of Cincinnati (UC) to conduct a long-term medical surveillance study on RCF workers. This continuing study has been in progress for over 20-years, collecting data from respiratory questionnaires, lung function tests, chest X-rays, exposure monitoring, and worker mortality. The results of this study of RCF plant workers exposed from 1953 to the present have shown:

- No excess mortality related to all deaths, all cancers, or lung cancer
- No statistically significant increase in interstitial findings (fibrosis), and
- No mesotheliomas

Thus, this long term epidemiology study has demonstrated both an absence of interstitial fibrosis, no increased mortality risk and no decrement in lung function associated with current exposures.

Since there has never been human disease associated with exposure to RCF, a risk assessment based on cancer endpoints in humans is impossible. Thus, RCFC commissioned a risk assessment based on the bioassay data from the animal studies described above which were conducted at RCC Laboratories in Geneva, Switzerland during the late 1980's. *Sciences International Inc.*, a world renowned environmental consulting firm, conducted the risk assessment in 1998 based on the RCF animal studies. The risk assessment team was led by Dr. Suresh Moolgavkar and utilized the two stage clonal expansion model.

The model looked at fiber lung burden in the animals along with deposition and clearance in both humans and animals, allowing for estimates of risk based on lung burden only. The calculated risk for a 70 year old worker with 30 years of exposure to 1

f/cc was  $3.7 \times 10^{-5}$  (maximum likelihood estimate) for a nonsmoker and  $1.5 \times 10^{-4}$  for a smoker. Further work by Moolgavkar and coworkers has shown the importance of fiber biopersistence on carcinogenic potential. Fiber chemistry influences carcinogenicity primarily through its role in biosolubility. Using the Moolgavkar work, Turim and Brown 2003 summarized the 95% upper bound risk of excess lifetime lung cancer for nonsmoking workers as:

- $3 \times 10^{-5}$  for a 1 f/cc exposure
- $1.5 \times 10^{-5}$  for a 0.5 f/cc exposure
- $0.3 \times 10^{-5}$  for a 0.1 f/cc exposure
- Separately, Fayerweather (1997) extrapolated rat data to human data using a linearized multistage model and found at exposures of 1 f/cc, the excess lifetime risk of developing lung tumors was  $3.8 \times 10^{-5}$  (maximum likelihood estimate).

Subsequently others have modeled animal data yielding similar risk estimates.

Pursuant to the PSP RCF manufacturers have undertaken a comprehensive analysis of all potential RCF exposure pathways. As discussed above, these efforts have been endorsed, and relied upon in lieu of regulation, by federal authorities at OSHA, NIOSH and EPA. The essential conclusion has been that occupational exposure is the only potentially significant human exposure pathway for RCF, and that the PSP has been effective in preventing harmful occupational exposure. The final regulations and Statement of Reasons should clarify that under these circumstances, existing regulation should be deemed to include industry product stewardship programs such as the RCF PSP.

### **Alternatives Analysis**

The prior regulations defined "feasibility," for purposes of potential alternative products, as follows:

As part of a determination of whether a “technologically and economically feasible alternative” exists, the responsible entity shall consider all of the following, to the extent applicable: (a) The extent to which a functionally acceptable alternative is currently available in the marketplace; (b) the affordability of any currently available functionally acceptable alternative; and (c) the purchase price differential between the Priority Product and the alternative.

The current proposal changes this:

"Technically and economically feasible alternative" means an alternative product or chemical for which: (A) The technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement the alternative, and to meet consumer demand after an appropriate phase-in period; and

(B) The manufacturer’s operating margin is not significantly reduced.

Unifrax urges the Department to retain the prior definition in the final regulations.

Feasibility determinations should be based on acceptable alternatives that are currently available, and the affordability of any such alternatives. It should not be based on speculation as to products that are "expected to be sufficient." The new definition will lead to required alternatives that have not been demonstrated to be feasible, and in fact are not feasible, in various relevant markets.

Unifrax also notes, as indicated above in the summary of RCF uses and potential exposures, that several of the other factors specified in the statute for evaluation of alternatives are particularly applicable to RCF. These include:

- Product function or performance
- Materials and resource consumption
- Air emissions
- Production, in-use, and transportation energy inputs
- Energy efficiency
- Greenhouse gas emissions

Unifrax urges the Department to adopt final regulations that include the prior definition of feasibility and state clearly that all of these factors are to be considered in the analysis of potential alternatives.

Conclusion

For the reasons stated above, the final consumer product regulations and accompanying Statement of Reasons should:

1. Reinstate the prior exemption for bulk chemical products;
2. Reinstate the prior exemption for existing regulation;
3. Clarify that existing regulation of a potential exposure pathway is adequate where additional regulation has been investigated and found to be unwarranted;
4. Clarify that existing regulation includes product stewardship programs that have been determined by regulatory authorities to provide adequate protection; and
5. Reinstate the prior definition of feasibility.

Respectfully submitted,



UNIFRAX I LLC

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

October 11, 2012

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

Re: Unilever's Comments to the Proposed "Safer Consumer Products" Regulation

Dear Ms. Von Burg:

We are contacting you with Unilever's comments on the proposed "Safer Consumer Products" regulation.

Over the past four years, Unilever, a global consumer products company with manufacturing facilities in California in City of Industry, Sunnyvale, and Stockton, has been participating in the California Green Chemistry Initiative through our industry trade associations, including the: Grocery Manufacturers Association (GMA); Personal Care Products Council (PCPC); American Cleaning Institute (ACI); the industry coalition known as the Green Chemistry Alliance (GCA); and, more recently, with the Consumer Specialty Products Association (CSPA).

We support the comments which these organizations are sending in separately, but there are several additional comments which we would like to make.

#### Introduction

Unilever manufactures a wide range of personal care products for the California market. We assess the safety of these products to ensure that they will be safely used by our consumers. We also ensure that we comply with both federal and state regulations.

For years, Unilever and our trade association representatives have lobbied in support of bipartisan measures to create a science-based framework for chemicals management. This was true in 2008 with the passage of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). The driving force behind industry's efforts has been a broad based desire for state regulators, rather than legislators, to exercise their expert scientific and engineering judgment and experience when promulgating appropriate regulatory provisions affecting chemicals of concern in consumer products.

The Green Chemistry Alliance (GCA) has advocated the crafting of regulations to enable the DTSC to fully and successfully implement AB 1879 and SB 509, which would provide for comprehensive chemical management and in turn enhance public health and environmental protection, promote innovation while still respecting confidential business information, and further the principles of sustainable development. In a proactive fashion

and in response to DTSC's requests for comments, GCA stakeholders have invested countless hours over the last several years developing regulatory text and comments for implementing the regulation. This work has been the result of a focused and proactive effort by a broad array of individuals from coast to coast with science, engineering, toxicology, R&D, manufacturing and legal backgrounds and possessing significant expertise in state, national and international chemical management policy.

We recognize the extensive DTSC staff efforts that have gone into the proposed regulatory revisions from 2011 and into 2012, plus the support of Director Raphael's efforts to make the Safer Consumer Products regulation "practical, meaningful, and legally defensible." Unilever is hopeful that, upon adoption, the final regulation will:

- 1) be forward-looking in order to identify, prioritize, evaluate and regulate the highest priority chemicals of concern in high priority consumer products;
- 2) promote truly safer alternatives on the basis of comparative multi-media life cycle evaluations;
- 3) consist of a comprehensive set of regulatory concepts that are within (a) the authority of and (b) fully satisfy the substance of the enabling legislation;
- 4) allow for a clear, timely and effective implementation in an orderly and economically responsible manner; and
- 5) provide clarity regarding compliance and enforcement.

#### Positive Features of the Proposed "Safer Consumer Product" Regulation

The proposed regulation contains a number of items which will help to create a program that could deliver the desired result.

- The regulations describe an approach which DTSC indicated will identify approximately 185 Chemicals of Concern (COCs) for the first 3 years of the program. Unilever supports the narrowing of the list of COCs, as long as information on the chemical hazard plus indicators of exposure to the citizens of California are used to prioritize and narrow the list of candidate COCs to a workable number.
- Unilever also supports the idea that, in the first round, DTSC will only pick up to 5 Priority Product/COC pairs to enable DTSC to learn, from actual case studies, what the issues are in implementing the regulation.
- The Alternative Analysis (AA) section of the current proposed regulation has some important improvements over earlier versions of the regulation. Unilever has spent considerable time and effort, notably in the workshop of September 15, 2011, to give examples of how our industry currently manages its everyday programs of assessing alternatives, for a wide variety of reasons. We support the fact that the proposed regulation expects companies to conduct alternatives assessments, using the skills in this area built up over many years, to reach their own conclusions on potential product changes, without having the answer pre-determined by DTSC, which, in all

due respect, does not have the years of experience in the formulation of consumer products that the companies have.

- Two additional positive changes are provided with the current proposed regulation: (a) elimination of the need for 3<sup>rd</sup> party verification; and (b) the added ability of being able to use in-house expertise to develop AA's. These changes will allow an alternative assessment to be completed more efficiently, since significant expertise resides in the companies, thereby allowing DTSC to reach its implementation goals more quickly.

## Issues with the Proposed "Safer Consumer Products" Regulation

There are still numerous concerns, however, which Unilever has regarding the proposed regulation. In our view, these must be addressed in order for the regulation to achieve its goal of providing improvements in the safety of consumer products. One overarching concern is that the inter-related requirements of the regulation will actually stifle true product and chemical alternatives innovation, simply because of the amount of unnecessary work that would be required even just to make a simple substitution of an ingredient. All this work requires resources, which will be otherwise diverted from focused innovation projects that serve as the lifeblood of all consumer product companies.

The goal of the underlying statute of AB 1879 is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products. However, the proposed regulatory approach could create an unpredictable framework which will only increase uncertainty for companies doing business in the state of California.

While Unilever supports the commitment by DTSC to life cycle thinking in evaluating alternatives to current chemicals of concern, there are other factors that are important to companies doing AA's which the proposed DTSC regulations have completely failed to address. For example:

### 69501.1(a)(56) Definition of Safer Alternative

The proposed regulatory definition used by DTSC is that a "safer alternative" "means an alternative that, in comparison with the existing Priority Product, reduces, avoids, or eliminates the use of, and/or exposures to, one or more Chemical(s) of Concern, so as to reduce adverse public health and environmental impacts".

This definition needs to be significantly changed. While using a "safer" alternative to a chemical of concern may theoretically result in a "safer formulation" for a given product, to the extent that there may have been a negative public health or environmental impact associated with the original product, the use of a "safer alternative" may not actually reduce any such risk.

In addition to evaluating the human and environmental safety of a product, including a proposed alternative product, consumer product companies also must ensure that the product be evaluated for microbiological and physical safety. It is possible to take the safest, “greenest” ingredients (i.e., “safer alternatives”) and make a toxic product if the product is manufactured in a hygienically unsafe manner or if the product is not preserved properly to prevent microbiological contamination and growth of microorganisms. As such, in order to prevent microbiological contamination, there may be times when certain minor amounts of chemicals may be required to ensure total product safety – even if the chemical is not deemed the safest alternative under the proposed regulatory program. So, the regulation needs to recognize the distinction between the potential risk associated with an ingredient versus the potential risk of the final product. Physical safety also includes the choice of packaging material, as some forms of packaging provide the consumer with the ability to use a product more safely (for example, using plastic packaging instead of glass for certain applications). If either of these issues are not addressed adequately, the final product could present significantly more acute safety issues to consumers than many of the supposed chemicals of concern in a product that are the subject of the “safer alternatives” concept.

## Legal Factors

Patent considerations and market availability must also be part of any alternatives analysis, as companies may be prevented from using DTSC’s preferred chemical or process simply because another company holds a patent for that preferred chemical and it is not willing to grant a license to another entity to use the patented preferred chemical. So, there needs to be regulatory recognition of whether the “safer alternative” is truly readily available in the marketplace. Clearly, DTSC would not mandate that a company violate a patent just because it considers its use to be a “safer alternative.”

## 69505.1.(e) Certified Assessors

Unilever has significant reservations about the role and qualifications of the certified assessor as set forth in the proposed regulations. DTSC states, in 69505.1.(e), that “each AA completed on and after the date that is two (2) years after the effective date of these regulations shall be performed by, or under the responsible charge of, one or more assessor(s) certified under article 8 for the appropriate product type or industry sector.”

As set forth in, Article 8 “Accreditation Bodies and Certified Assessors,” of the proposed regulations, DTSC is under the mistaken notion that mere academic training can provide enough knowledge for a person to be able to either conduct or lead a robust alternative assessment. Two (2) years professional experience is not enough to be fully aware of the intricacies of formulating consumer products, and personal care products in particular, and post-graduate work in the performance of AA’s just cannot substitute for the two (2) years of professional experience. Significant experience in the laboratory is typically required for a formulator to know how to develop formulations that are stable and safe for several years, provide the benefits expected by consumers at a cost that they can afford, and then apply that to new ingredients. Five (5) – ten (10) years of experience working as a formulator or

processing engineer in a company making consumer products should be the minimum experience required, along with significant experience and training in project management. Global companies may also not have the correct academic and accreditation requirements as required by DTSC; global companies will likely have to rely on global formulation teams based outside the United States. As such, the final regulations will need to have the requisite flexibility to accept the qualifications of certified assessors from around the globe.

The proposed Article 8 assessor training and certification programs are also far too ambitious. To successfully develop a product for the consumer market requires the melding of many different skills, including chemistry, chemical engineering, packaging engineering, microbiology, toxicology, environmental toxicology, manufacturing, quality, occupational safety, finance, consumer insight (psychology, for example), marketing and more. The requirement that one person, especially one with so little real experience in formulation chemistry, to show expertise in all these fields is just not realistic. Unilever has Ph.D's in many of these fields; they are experts in their respective fields and have many years experience and knowledge in that field, but not in other facets of formulation. Developing and bringing a safe and successful product to market is the result of the combined efforts of these experts plus years of experience in making it all come together.

For many global companies the AA's will be conducted outside of the U.S.; California must make it possible for assessors to come from any geographic location.

If a certified assessor is hired by a company to conduct the AA, that company also has to ensure that the assessor is bound by strict confidentiality requirements. The assessor, to do the job adequately, will not only have to obtain confidential information about formulations but also the manufacturing and supply chain capability of the company.

Unilever proposes that the role of certified assessor be eliminated in favor of developing a list of guidelines, or checkpoints, that need to be addressed when conducting an AA. When DTSC receives the formal AA reports, it can quickly ascertain whether the appropriate factors have been evaluated. Any training that is to be done should be given to DTSC staff who review the AA reports.

#### 69508.1: Qualifications for Accreditation Bodies

As noted above, academic knowledge in various fields, without significant experience in formulation, processing, or manufacturing consumer products does not provide enough knowledge to become accredited to train and certify assessors. In many cases those conducting an AA will have significantly more experience than the accreditation body, a case which could lead to significant issues when there are disagreements.

The proposed accreditation program is unnecessarily bureaucratic and will not provide better assessors, since company expertise will still be the tools that companies will use to determine better alternatives, as they have done for many years. The accreditation program proposed would be better suited to helping develop guidelines for conducting

an AA and to provide additional training to DTSC in areas where staff members are not already experts.

69501.2.(b)(1)(B) plus other relevant sections such as 69501.2.(b)(2)(A)(2) and 69505.5.(d)(3): Notification of Persons who purchased product

The regulation requires that the manufacturer of a Priority Product provide to DTSC “the name of, and contact information for, all persons in California, other than the final purchaser or lessee, to whom the manufacturer or importer directly sold the product within the prior twelve (12) months....”

This requirement is impractical, since we sell products to many retailers and distributors located outside California who in turn bring products into the state. A manufacturer thus is not in a position to know the name and contact information for all such persons in the state of California, since we do not sell directly to these people.

We recommend that DTSC eliminate this requirement to notify all those who sell the product in the state of California, as it will not provide any benefit to consumers and will not serve to advance the goals of the legislation.

## Conclusion

Unilever has a long history of providing safe, sustainable products to the consumers in California. Our brand names are major assets in signifying the value which we deliver to consumers, and we take great care in ensuring that we meet the consumer needs in a safe and sustainable manner. While we support the goals of the legislation, we want the regulation to provide the greatest opportunity for innovation without the interference of overly burdensome compliance measures.

If you have any questions regarding our statements, don't hesitate to contact me.

Regards,

Dr. Jack Linard  
Head Regulatory Affairs Personal Care NA  
Unilever  
800 Sylvan Avenue  
Englewood Cliffs, NJ 07632

201-894-6513  
jack.linard@unilever.com

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## GCREgs@DTSC

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**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Ron Christensen; Pam Sexton  
**Subject:** Question on SCP - A

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #A:

While you expect us to publicly comment on this regulation before September 11th, why is not the complete proposed Chemicals of Concern List provided for our public review?

Background:

On page 24 (of 78) in SAFER CONSUMER PRODUCTS Proposed Regulations, R-2011-02, at your weblink <http://www.dtsc.ca.gov/upload/SCPProposedRegulationsNoUnderlineJuly2012.pdf>, you have written (at lines 11 through 14) the following:

" § 69502.3. Chemicals of Concern List.

(a) The Department shall post an informational list of the chemicals identified as Chemicals of Concern under section 69502.2(a) on the Department's website within thirty (30) days after the effective date of these regulations."

Additional Comment:

We would expect to be able to read the complete regulation with all of its components, including an initial listing of identified explicit chemicals!

Respectfully submitted,  
Gary Valasek

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[YOUR EMAIL in TEXT FORMAT]

Department of Toxic Substances Control  
July 27, 2012

Dear Regulations List Subscriber:

The Department of Toxic Substances Control (DTSC) has submitted a new rulemaking proposal to the Office of Administrative Law (OAL) for review and public comment. We are sending you this notification because you have expressed an interest in DTSC's rulemaking activities.

Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

Department Reference Number: R-2011-02

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

Public Comment Period: July 27 - September 11

The Public Notice and all related documents will be posted at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/index.cfm> and <http://www.dtsc.ca.gov/SCPRegulations.cfm>.

If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

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## GCREgs@DTSC

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**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Ron Christensen; Pam Sexton  
**Subject:** Question on SCP - B

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #B:

What documentation is being published for public review (within the July 27-September 11 public comment period) that supports each of the chemicals on the initial Chemicals of Concern List?

Respectfully submitted,  
Gary Valasek

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[YOUR EMAIL in TEXT FORMAT]

Department of Toxic Substances Control

July 27, 2012

Dear Regulations List Subscriber:

The Department of Toxic Substances Control (DTSC) has submitted a new rulemaking proposal to the Office of Administrative Law (OAL) for review and public comment. We are sending you this notification because you have expressed an interest in DTSC's rulemaking activities.

Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

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If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).

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## GCREgs@DTSC

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**From:** Gary Valasek <GValasek@www.icc-chemicals.com>  
**Sent:** Monday, July 30, 2012 8:40 AM  
**To:** GCREgs@DTSC  
**Cc:** Pam Sexton; Ron Christensen  
**Subject:** Question on SCP - C

7/30/12

Thanks for your email of Friday, July 27, 2012, whose text is provided at the bottom of this email. At your behest, we are submitting this question, accordingly:

Question #C:

What was the criteria to drop the number of Chemicals of Concern from ~3000 in October 2011 to ~1200 in July 2012?

Background:

Item#1:

Your 16-page document of 10-31-2011 found at

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Regulations-Informal-Draft-Summary-10312011.pdf>,

provides on page 2 the statement that the "regulations establish an immediate list of Chemicals of Concern (~3,000)..." and

your 5-page document of July 2012 found at

<http://www.dtsc.ca.gov/upload/SCPProposedRegulationsChangesJuly2012.pdf>,

provides on page 1 the statement that "the list will include ~1,200 COCs.....".

Item#2:

An interesting example of the workability of chemical criteria is found in the Federal EPA TSCA at

<http://www.epa.gov/oppt/existingchemicals/pubs/wpmethods.pdf>

where EPA has shown transparency and accountability in their process of handling Work Plan Chemicals.

Respectfully submitted,

Gary Valasek

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[YOUR EMAIL in TEXT FORMAT]

Department of Toxic Substances Control

July 27, 2012

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Proposed Regulation: SAFER CONSUMER PRODUCT ALTERNATIVES

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If you have any questions or comments, please email DTSC at [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov).  
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October 11, 2012

**VIA E-MAIL**

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

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

**Re: Proposed Safer Consumer Products Regulation  
Comments from Valero  
Department Reference Number: R-2011-02  
(Division 4.5, Title 22, California Code of Regulations, Chapter 55)**

Dear Ms. Von Burg:

The Valero Companies (“Valero”) appreciate this opportunity to provide these comments regarding the Department of Toxic Substances Control’s (“DTSC”) proposed regulation for Safer Consumer Products (SCP), as posted for public comment on July 31, 2012. Valero owns and operates two refineries in the state of California with a combined throughput capacity of over 305,000 barrels per day and markets our products on a retail and wholesale basis through an extensive pipeline distribution system. Valero is one of the nation’s largest retail operators with a significant presence in California as well as 37 other states.

We strongly urge DTSC to provide a specific exemption and/or exclusion for all transportation fuels from the SCP regulation. The goal of the SCP regulation is to “create a systematic, science-based process to evaluate chemicals of concern, and identify safer alternatives to ensure product safety.” Valero supports such measures when applied in a manner that recognizes both products that are already inherently “safe” and products that are handled to such an extent that risks are minimized to ensure product safety. The definition of “consumer product” currently used by the regulation is extremely broad and can be construed to include transportation fuels, thereby subjecting all refined fuels produced for use in California to the SCP alternative analysis and potential reformulation requirements. Valero contends that transportation fuels, for the reasons outlined below, are already regulated and managed to an extent that ensures product safety and minimizes chemical risks, obviating the applicability to the SCP rule. We further contend that the SCP regulation is an inappropriate tool to apply to such ubiquitous and fungible products as transportation fuels, as the scope of impacts would extend far beyond the refiner to the entire distribution infrastructure. Finally, Valero incorporates by reference the comments and recommendations submitted by the Western States Petroleum Association (WSPA) submitted on October 11, 2012.

**1. Transportation fuels are already heavily regulated/reformulated to ensure product safety**

Transportation fuels have been the subject of increasingly-stringent regulations since the 1990's that impact both the fuel formulation as well as how fuels are handled, shipped, and stored. For instance, fuels have been reformulated to reduce toxics through the following:

- MSAT (2007): Reduced emissions of benzene, formaldehyde, naphthalene, and other air toxics. Lowering the benzene content in gasoline and reduced evaporative emission from fuel containers.
- RFG (1995 and 2000): Required cleaner burning formulations to reduce smog formation and toxic pollutants.
- Tier 2 (2000): Reduced sulfur content of gasoline by 90%
- RVP and seasonal blending (1990): Reduced volatility of fuels to limit evaporative losses and limit ozone formation
- RFS 1 and 2 (2007) and (2011): Requires the use of specific volumes of renewal fuels derived from biogenic sources.
- Toxic Substance Control Act (TSCA): Regulations specifically geared towards identifying substances of concern, their use and distribution in commerce, and the subsequent regulation and/or prohibition thereof.

In the context of safety regulations, transportation fuels are governed by the following:

- DOT regulations prescribing truck, rail and ship loading and handling obligations
- PHSMA regulations prescribing pipeline movements of transportation fuels
- OSHA regulations prescribing safety requirements on fuel dispensing equipment

There are additionally many state and/or local requirements not listed here that are already in effect. Regulation of fuels under these federal programs continues, with some rules continuing to phase-in newer and more stringent requirements over time. In the aggregate, there are a tremendous number of regulations that not only dictate the composition of transportation fuels to limit toxics, but also the physical handling, shipping, and dispensing of such fuels, all with the common goal reducing risk to human health and the environment. Valero contends that "product safety" with regards to transportation fuels has already been well addressed and further regulation through the SCP process will not provide any additional benefits or further "ensure process safety".

**2. The definition of "Consumer Products" should be applied in a manner commensurate with the goals of the regulation**

In the context of the CPS, a very broad reading of the term consumer products appears to conflict with the goals of the regulation. The CPS regulation is clearly geared towards those "consumer products" for which more frequent and/or intimate contact is common, thus increasing any risk of potential exposure. Cosmetics, clothing, food packaging, carpets, house paints, and furniture coatings: all of these are substances for which direct use involves a high degree of physical contact and exposure. Transportation fuels, through the regulations cited above, are in a very different category of materials, with limited exposure pathways and extant safer product formulations. Given the magnitude of the undertaking involved in the CPS, it is in the interest of DTSC to focus resources on those products for which the regulations are designed by supporting a limited definition of "consumer products" that omits those substances which are already heavily regulated in this regard.

**3. Transportation fuels are primarily a natural occurring substance that present unique problems when reformulating**

Many typical consumer products owe their formulations to deliberate and specific processes that require the production and/or addition of certain chemicals. If formulation requirements change, either the process can be adjusted or different chemicals for feedstocks are purchased. However, many of the substances that would potentially be targeted by the CPS rule are naturally occurring in the crude feedstocks, which present limited options when reformulation is required. An increasingly complex arrangement of separation and conversion process units at refineries must be constructed in order to remove and/or convert material into something usable in the transportation fuel pool. This was a significant undertaking with MSAT compliance, requiring years of planning, permitting, and construction. With the bulk of toxics already regulated or even eliminated, the remaining options available to refiners become increasingly exotic and expensive. Valero contends that the limited scope of solutions available to further reduce specific substances in refining products will not prove cost effective and we urge DTSC to perform this cost-benefit analysis in light of the heavy regulations already in place.

**4. Applying this rule to transportation fuels will potentially have downstream “unintended consequences” beyond those considered by the regulation.**

If the proposed SCP regulation was applied to transportation fuels, the impacts would extend far beyond modifications to the refining process. The entire supply chain – pipelines, rail, trucking, terminaling, even to the extent of impacting motor vehicle performance – would potentially be affected.

- Cross contamination will be a significant consideration if any fuel specifications vary considerable from those in current CARB-BOB and CARB Diesel. This situation would require special handling not only for storage at the refinery (requiring additional storage tanks) but in all modes of transport and storage downstream. Trucks and rail cars would require either dedicated service to the new formulation or require cleaning when changing between formulations. Downstream terminals, who could potentially store CARB-BOB and conventional gasoline without cross contamination driving the product “out of spec”, would now need additional, dedicated storage to handle the new formulation. Building the infrastructure to maintain compositional integrity of an additional transportation fuel would require significant capital expenditures across the entire fuels industry from refinery to retail. Further, this infrastructure would require permitting and significant construction time beyond the manufacturers’ purview, creating significant delays in the overall execution of the goal of getting reformulated products to market.
- The impact on vehicle operations due to the transition from conventional to low sulfur diesel is well documented. In removing a portion of sulfur and aromatics from diesel, fuel leaks developed from some vehicles due to shrinkage of the O-rings/seals on fuel pumps and injectors. This was a largely unforeseen consequence of the transition to “cleaner” fuels and the impact on downstream equipment. Lacking a detailed understanding of the chemistry involved in the reformulation of fuels required under the SCP, similar unintended consequences are possible, particularly given how motor vehicles are designed with increasingly exotic materials under very specific operation condition. In order to prevent the possibility of similar scenarios occurring under the SCP rule, any potential fuel reformulations considered would require extensive testing and review with the engine manufacturers before execution at the refinery level. The current proposal does not contemplate this time-consuming and expensive testing phase, instead only requiring affected industries to submit plans on the process changes necessary to meet DTSC’s predetermined

formulation for toxics reduction. The end result would potentially be a significant disruption at the consumer level.

**5. The proposed rule is insufficiently defined to provide adequate comment opportunities to potentially affected industries**

While the SCP proposal outlines in detail the process of determining Chemical of Concern (COC), and the regulations of these chemicals thereof, the draft regulation fails to provide the details necessary to determine 1) which industry or business will ultimately be impacted by this regulation, and 2) what chemicals will be regulated. Lacking the regulatory definition of either the chemicals to be regulated or the industries that would ultimately be impacted, we contend it not possible for the public review and comment requirements of the regulatory process to be sufficiently observed under the law. The universe of businesses and chemicals that may be regulated is lacking any boundaries and conditions such that industry would know where and how to provide meaningful comments. This type of “open-ended regulation” circumvents public notice and comment requirements by drafting regulations lacking in the details necessary for industries to understand who and what is regulated. At a minimum, DTSC should provide the list of COCs with this draft regulation so as to afford affected parties an opportunity to identify, in a tangible and quantifiable way, if they could be affected under this rule.

**6. DTSC should provide clarification that “consumer products” cannot be construed to include materials outside of retail transactions**

The definition of “Consumer Products” used under this regulation is found in the Health and Safety Code Section 25251:

- (e) "Consumer product" means a product or part of the product that is used, brought, or leased for use by a person for any purposes. "Consumer product" does not include any of the following:
- (1) A dangerous drug or dangerous device as defined in Section 4022 of the Business of Professions Code.
  - (2) Dental restorative materials as defined in subdivision (b) of Section 1648.20 of the Business and Professions Code.
  - (3) A device as defined in Section 4023 of the Business of Professions Code.
  - (4) A food as defined in subdivision (a) of Section 109935.
  - (5) The packaging associated with any of the items specified in paragraph (1), (2), or (3).
  - (6) A pesticide as defined in Section 12753 of the Food and Agricultural Code or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. Sec. 136 and following).
  - (7) Mercury-containing lights defined as mercury-containing lamps, bulbs, tubes, or other electric devices that provide functional illumination.

Valero contends that this definition of “Consumer Product” is so broad as to encompass the sale of materials and products outside the realm of retail transactions, to instead include wholesale and bulk purchases between industries. The implications of this broad reading are significant as they could include crude oils, intermediates, and other hydrocarbon materials purchased by refineries as feedstocks. Chemicals purchased in-bulk by refineries, necessary for industrial operations, would also be impacted. We highly recommend that DTSC tailor the definition of “Consumer Products” so as to clearly exclude potential misinterpretations such as these and instead focus the definition to those products available to consumers at the retail level only.

Valero strongly urges DTSC to revise the proposed rule consistent with Valero's comments. We contend that transportation fuels have already been reformulated and are safely handled under the current federal and state regulations to "ensure product safety", obviating the need to reassess fuels under the SCP. Providing an exclusion for transportation fuels will keep the execution of the SCP rule consistent with the intent of focusing on those products for which society has direct and regular contact. It will also prevent any unintended consequences of infrastructure overhaul and equipment incompatibilities at the consumer level.

We look forward to working with DTSC on further rule development and the promulgation of a final rule that is reasonable, technically feasible, and cost effective. Please contact me at (210) 345-4620 should you have any questions or need clarifications concerning our comments.

Sincerely,



Matthew H. Hodges  
Director, Regulatory Affairs  
Valero Companies  
210-345-4620  
[matt.hodges@valero.com](mailto:matt.hodges@valero.com)

## GCREgs@DTSC

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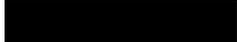
**From:** Mary Vernier <vernier.mary@gmail.com>  
**Sent:** Tuesday, October 09, 2012 7:52 AM  
**To:** GCREgs@DTSC  
**Subject:** California Department of Toxic Substances Control (DTSC) issued newly revised proposed regulations

Ms. Von Burg,

I am a small business owner, revenue in the \$5,000 range. My main product is Handcrafted Soap. The only way to make soap is to use Sodium Hydroxide (lye). I am concerned with the proposed changes and the impact that will have upon my business. The financial impact needs to be assessed at all revenue levels. Please contact the Handcrafted Soap Makers Guild organization in regards to work that has been done at the Federal level for our business. I am linking the HSMG web site below:

[Handcrafted Soap Makers Guild](#)

Thank you in advance for your consideration in this matter.

Mary Vernier of Mary's Green and Clean Handcrafted Soaps  




Submitted via Electronic Mail, October 11, 2012

California Department of Toxic Substances Control  
1001 I Street, P.O. Box 806  
Sacramento, CA 95812-0806  
[regs@dtsc.ca.gov](mailto:regs@dtsc.ca.gov)

**Re: Safer Consumer Products regulations (file number Z-2012-0717-04).**

Dear Sir or Madam:

The Vinyl Institute appreciates the opportunity to file these comments on proposed Safer Consumer Product regulations issued by the Department of Toxic Substances Control. The Vinyl Institute is an independent trade association representing U.S. producers of polyvinyl chloride resin and other materials that go into myriad vinyl products that people rely on every day.

In general we are writing to express our support for the comments filed by the American Chemistry Council (ACC). In particular, we are concerned about the costs, confusion, and potential disruptions to the businesses of our members, without significant public benefit, that may result if these regulations are finalized in their current form.

We do not understand the criteria by which DTSC will identify, prioritize, and evaluate hundreds of chemicals "of concern." Without more specific and objective criteria, chemicals that have proven safe and useful through long use in important products could be threatened with stigma, if not restrictions.

We urge DTSC to revise the regulations so as to adopt a clearer, more workable approach to reviewing chemicals in consumer products. As ACC has suggested, such an approach would identify chemicals that pose potentially significant consumer product hazards that have not been addressed by existing federal or state laws and regulations. These substances would be subject to priority review using established protocols. Any alternatives assessments deemed necessary would be subject to a comparably rigorous review process. Criteria should make clear how substances might "pass" such a review and should establish that substances that did pass would not be subject to further evaluation unless new information suggested a need.

We would be happy to discuss our concerns in further detail.

Sincerely,

Allen Blakey,  
Vice President, Industry and Government Affairs

# ALSTON & BIRD LLP

1115 11<sup>th</sup> Street  
Sacramento, CA 95814

916-498-3305  
Fax: 916-441-5449  
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**Maureen F. Gorsen**

**E-mail: [maureen.gorsen@aalston.com](mailto:maureen.gorsen@aalston.com)**

October 11, 2012

VIA EMAIL

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

VIA MAIL

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

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

Dear Ms. Von Burg:

On behalf of Dr. John Warner, President and Chief Technology Officer of the Warner Babcock Institute for Green Chemistry ("Warner Babcock Institute"), we are pleased to submit the following comments regarding the Department of Toxic Substances Control's ("Department") proposed regulations to implement California's ground-breaking safer chemicals statute.

At the Warner-Babcock Institute, Dr. Warner is dedicated to the development of non-toxic, environmentally benign, and sustainable technological solutions for society. Dr. Warner believes that California has a tremendous opportunity to advance the development of green chemistry globally. Dr. Warner was honored and pleased to have had the opportunity to serve as Chair of the Green Chemistry Initiative Science Advisory Panel, which was convened in the fall of 2007 and finalized its recommendations and submitted its report to the Department in May 2008 (attached as Exhibit A.) Many of those recommendations were incorporated into the green chemistry laws that California enacted in November 2008. So now that the Department is poised to develop regulations to implement that statute, those initial recommendations should be revisited as many are absent from the current proposal.

The Department's proposed regulations are too heavily-focused on demand-side considerations, and give short shrift to supply-side considerations that are necessary to

bring the promises of a future that is benign by design. The alternatives analysis contained in the Initial Statement of Reasons does not indicate that much thought was given to supply-side considerations, nor alternative regulatory designs considered that could bring about the beneficial changes envisioned by the statute.

In the intervening years since the Science Advisory Panel issued its final recommendations, Dr. Warner has given this problem of the appropriate regulatory design much thought and reflection. Below is an outline of an alternative regulatory design that the Department should consider prior to adoption of the proposed regulation. He strongly believes this regulatory structure will accelerate the development of green chemistry and focus the efforts of industry and societal resources to those activities that will be of greatest benefit to the State of California and bring to fruition its ambitious aims to remake the way the world makes things.

### **Elements of Safer Chemicals Policy**

#### **A Regulatory Design to Accelerate Move to Safer Chemicals and Safer Consumer Products**

The outline below provides an opening discussion of five (5) elements of a safer chemicals policy. It is not intended to be prescriptive, but provides suggestions of a framework for moving forward.

##### **Element 1. Move from a list based system to an assay based system.**

For the past several decades, we have spent a great deal of time and effort focusing on identifying molecules of concern. Debate and controversy arises because people disagree on what the appropriate tests and methodologies should be. Much progress could be made if we focus our efforts on agreeing on what tests and assays we should be used to evaluate toxicity and environmental impact. If done correctly, this process will move us away from the “molecule by molecule” system towards an assay based system. By identifying the correct assays necessary to evaluate a product, we will significantly reduce cases of unfortunate substitutions. Having these criteria ironed out will provide industry with much needed guidance of what society deems as “safe.”

Without these criteria firmly in place it is difficult for industry to rationalize the significant investment necessary to invent safer alternatives. In our present system, the uncertainty of how new molecules will be evaluated, sometimes makes the investment in safer alternatives too risky. By identifying the various required assays, research organizations will be able to perform toxicology experiments during the early stages of research and thus be more cost effective and efficient.

Element 2. Move from a molecule based system to a product based system.

There are several tens of thousands of molecules in commerce. It is essentially impossible to evaluate or test them all. Many products or components of products consist of hundreds of different molecules. It is inappropriate to characterize a product as “safe” merely because it does not have a molecule that appears on a list somewhere. This method leads to unfortunate substitutions. The way to be better informed as to the impacts of a product on human health and the environment is to test the entire product (or subsets of components). This element is not designed to evaluate the *exposure* of any of the components or products to humans or the environment, but identifies that there exists within the product a compound that is giving a negative result on the assays identified in Element 1. The methodology of testing different physical states of materials will have to be addressed in the assay list developed in Element 1. If all the components of a product “pass” the assays identified in Element 1, then we can assume that based on the current level of knowledge, the product is likely “safe”.

Element 3. Identify and disclose hazardous materials.

When a product (or a component) fails an assay from Element 1, the company should be required to identify what assays the product failed. The company should document that a thorough alternatives assessment was performed to make sure the best available materials are being used. The company should perform an assessment of impacts in the (1) manufacture, (2) use and (3) disposal of the product and document plans to mitigate these impacts. If compelling evidence is provided documenting that the exposure to humans and the environment are appropriately controlled, the product should be allowed to enter commerce. In this case, the product should have appropriate labeling that identifies which assays from Element 1 have not been passed. The advantage of this approach is that company trade secrets are protected. No compound is ever identified, what is listed is that “some compound” in this product failed a certain assay.

Element 4. Focus on long term solutions.

When a product fails an assay from Element 1 and the company brings it to market with appropriate labeling, they should document their long term plans to help invent new safer alternatives. Depending on the size and nature of the organization, the level of involvement in inventing replacements should be commensurate. An organization within the Department should be formed to help companies articulate their technical needs and communicate these needs to the research community. This list of needs can help provide voluntary prioritization for various funding opportunities in both government and the private sector. Public workshops and conferences should be convened to alert the research and finance community of the needs and opportunities available. These workshops and conferences should bring together individuals describing

product needs and requirements, and people from toxicology and health sciences to discuss the mechanisms of harm so that new materials can be invented.

Element 5. Focus on jobs creation and workforce development.

The State should set up several “workforce development centers” to train high school graduates, 2-year college students and displaced workers. These people should be trained in competitive high-tech skills in the analytical/biotechnology industries. The hands on training should involve the execution of assays listed in Element 1. Sufficient oversight and redundancy will be necessary to ascertain quality. These centers should be fee-based with a plan to eventually become financially self-sustaining. Reduced rates can be provided to manufactures in state, providing an incentive for in state manufacturing.

With its groundbreaking safer chemicals law, California is in a unique position to play a global leadership role in creating the regulatory platform and infrastructure to stimulate the kinds of investment that are going to be necessary to bring about the invention of greener chemistries.

Five years ago, the Department commenced the Green Chemistry Initiative. The energy and enthusiasm for that Initiative has waned as the ideas that inspired so many have become mired in a regulatory bog that has lost its path. The Department has the opportunity to renew the energy and excitement for the promise and change that green chemistry can bring. To start fresh and reinvigorate industry in investing in a safer chemicals future, Dr. Warner urges the Department to immediately establish three committees described below and being in earnest a discussion on his five elements for a safer chemical policy.

Briefly, the suggested committees are described below.

Assay Committee: A diverse set of stakeholders to create a set of tests and assays that quantify toxicity and environmental impact. They should create the initial set of assays and describe the process of review and updating.

Compliance Committee: A diverse set of stakeholders to describe how testing protocols and data management will be certified and documented. They should create the initial plan and describe the process of review and updating.

Approval Committee: A diverse set of stakeholders to determine how materials that perform unacceptably in the assays should be handled. They should create the initial set of criteria describe the process of review and updating.

Dr. Warner would be pleased to work with the Department’s regulatory staff to develop the technical and regulatory language necessary to implement this alternative

Ms. Jones, DTSC  
October 11, 2012  
Page 5

regulatory design, or his assistance in developing the committees and working with stakeholders to develop this proposed five element framework.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Maureen F. Gorsen".

Maureen F. Gorsen

Attachments

Exhibit A: Green Chemistry Initiative Science Advisory Panel Final Report (May 2008)



October 9, 2012

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

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

Dear Ms. Von Burg:

The Water Quality Association (WQA), as a Green Chemistry Alliance (GCA) coalition member, joins many other associations and companies in opposing the state of California's proposed Safer Consumer Products Regulation, or Green Chemistry rules. We believe that the draft regulations are extremely unclear and a potential harm to consumers and the economy.

Our members, which include major manufacturers and sellers of water treatment products, have demonstrated an ongoing commitment to green products and environmental sensitivity. At the same time, they must have as much certainty as possible about regulatory schemes as they plan for the future.

The WQA respectfully submits the following comments relative to the Department of Toxic Substances Control's (DTSC) proposed Safer Consumer Product Alternatives Regulation of July 2012.

We believe the proposed regulations do not include a clear or science-based process by which the DTSC will ultimately select which chemicals and products it regulates. As written, it appears the regulation would also give the department full discretion to impose whatever remedies it chooses for violations. This would include imposing product restrictions to outright bans, or any approach the department decides on. It is hard to imagine companies being able to successfully plan new products with such uncertainty facing them.

We are concerned that our larger members could face significant costs associated with compliance, and smaller companies might find compliance simply impossible. No company, regardless of size, can determine from these regulations exactly how they will impact the ability to invest in, produce or sell a given product.

It is also troubling that the department's own economic analysis of the regulations concluded the impact to the state's economy is "unknown." In a time of economic struggle and high unemployment, it is critical that there be a clear understanding of the potential impact any regulations could have on jobs and the state's economy.

Safer products can be developed without placing new costs on consumers or endangering much-needed economic development in California. We believe the GCA has proposed workable, specific fixes to the key problems in the current draft regulations.

Thank you for your attention to this significant concern. As always, we look forward to working with policy makers and interest groups to find solutions that will work for everyone.

If you have any questions, please feel free to contact David Loveday at 630-505-0160.

Sincerely,

A handwritten signature in black ink, appearing to read "David Haataja". The signature is fluid and cursive, with a large initial "D" and a long, sweeping underline.

David Haataja  
Executive Director

*WQA is a not-for-profit association that provides public information about water treatment issues and also trains and certifies professionals to better serve consumers. WQA has more than 2,500 members internationally. WQA provides Gold Seal certification for products that remove a variety of contaminants. These products are tested according to independently developed standards of the highly respected ANSI (the American National Standards Institute).*



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

**Catherine H. Reheis-Boyd**  
President

October 11, 2012

Via email (gcregs@dtsc.ca.gov)

Ms. Debbie Raphael (Draphael@dtsc.ca.gov)  
Director,  
Department of Toxic Substances Control  
1001 I Street,  
Sacramento, CA

**RE: Comments on Proposed Revisions to Safer Consumer Product Alternative (Green Chemistry)**

Dear Ms. Raphael:

The Western States Petroleum Association (WSPA) is a trade association that represents 27 companies that explore for, produce, refine, market and transport petroleum and petroleum products in the Western U.S. WSPA members have extensive operations in California and are directly affected by regulations that may govern the use, manufacturing, handling and disposal of petroleum products including crude oil, transportation fuels, solvents, coatings, and lubricants among many other products.

As you know, WSPA has been actively engaged in the policy discussions relating to passage of legislation that enabled the action by the Department of Toxic Substances Control (DTSC) as you initially proposed, and later the revised the draft Safer Consumer Product Alternatives (Green Chemistry) regulations.

We understand that the primary objective of the Safer Consumer Product Alternatives (SCPA) regulation is to incentivize responsible entities to identify, develop and implement processes that improve consumer products by designing them to be "safer" for both consumers and the environment, i.e., "benign-by-design". However, based upon our review of the proposed regulations, Initial Statement of Reasons, (ISOR) and recent communications by the DTSC, the proposed SCPA regulations will likely create many unintended and adverse consequences that could frustrate achievement of this objective.

We agree with the DTSC that a process that incentivizes incremental product improvement is more likely to be embraced by manufacturers on a voluntary basis and result in public health and environmental benefits. We have identified areas within the regulations that could be modified to improve the focus of the regulations.

### **Proposed Regulation is Vague and Undefined**

As currently proposed, the regulations provide no clear guidance to the agency or stakeholders. Specifically, the proposed regulations provide no criteria, standards or methodology for designating chemicals of concern (CoCs), prioritizing products, identifying of Alternative Analysis Threshold (AAT) values, conducting Alternative Analyses (AA) or procedures for identifying which alternative results in a “safer” product.

### Lack of Clear Criteria, Standards and Methodology Limits Informed Planning

The DTSC has indicated that it seeks to utilize “market forces” as a primary means to further the “benign-by-design” objective of the SCPA. However, the lack of clear criteria, standards, and methodology in the proposed regulations limit the ability of responsible entities to make informed planning decisions to assure compliance with the regulation. In other words, lack of clarity on these key issues can inhibit responsible entities from accurately estimating environmental and economic costs and benefits that influence “market forces” and thereby slow the process of designing “safer” products, and in specific alternatives for individual products. This condition can leave consumers with fewer choices at higher costs which clearly is an undesirable market outcome.

### Derivation of Alternative Analysis Threshold (AAT) Values

Another example of a lack of specific criteria, standards and methodology is how an AAT value is to be derived under §69503.5. We understand that the purpose of the AAT value in the SCPA program is similar to that of USEPA Region IX Regional Screening Levels (RSLs)<sup>1</sup> under the DTSC’s site mitigation and remediation program. We also understand that the intent is to improve administrative efficiency for both responsible entities and the DTSC by focusing the limited resources of both groups upon those conditions truly warranting more detailed evaluation, thus reducing total assessment and compliance costs for both groups.

However, §69503.5 provides no clear criteria, standards, and methodology for deriving an AAT value. Instead, §69503.5 (c)-(e) merely identifies an assortment of factors that the DTSC may consider in deriving an AAT value. How and which of these factors are to be considered is unstated. Thus, each AAT could be developed *de novo* for each priority product in an *ad hoc* manner.<sup>2</sup>

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<sup>1</sup> RSLs were formerly known as Preliminary Remediation Goals or PRGs. See <http://www.epa.gov/region9/superfund/prg/> for more information regarding USEPA Region IX Regional Screening Levels.

<sup>2</sup> It seems that §69503.5(c)(2)(B) establishes the floor for the AAT value at the “minimum detectable concentration” of the CoC while the other listed factors are considered by the DTSC in unspecified *ad hoc* manner to derive several ceiling values for each factor. How the DTSC uses this information to derive the AAT value is unstated. Other questions are raised by the term “minimum detectable concentration” of the CoC as it is undefined. Does it mean the reporting level for a specific analytical laboratory for a specific chemical CoC in a specific media on a specific date?

In contrast to this approach, RSL values are derived in accordance with written guidance in a uniform and consistent manner that is transparent to stakeholders.<sup>3</sup> While the DTSC may intend to limit its expenditure of resources by substituting the limit of analytical detection for development of a product-specific AAT, failure to address the risk-based factors in §69503.5 (c)(3) will likely lead to stakeholder objections in the product prioritization process under Article 3 and petitions under Article 4 seeking development of product-specific AAT values. The limit of detection approach also lacks the rigor necessary to screen low risk products out of the regulatory process and therefore has little value to DTSC as a means of managing program resources and workload.

Recommendation: At a minimum, we suggest that the DTSC should consider developing AAT guidance to be used in both the priority product identification process and the petition process. Doing so will likely support the following goals:

- Enhance transparency to stakeholders as to how the DTSC shall derive AAT values;
- Permit “market forces” to work more efficiently by informing responsible entities of how the DTSC will implement this provision of the regulation; and
- Reduce unnecessary delays and reduce overall compliance costs incurred by both DTSC and responsible entities.

#### Designation of Priority Products

Another concern with the proposed regulations that is potentially exacerbated by the lack of criteria, standards, and methodology, is the discretion retained by the DTSC in the identification of priority products. We believe that the proposed regulations could result in the misallocation of resources caused by the nearly unlimited scope of products that maybe identified as priority products. This concern was recently expressed by responsible entities at the September 10 hearing in comments associated with products ranging in scope from very simple single component products such as bar soap, household cleaning liquids, etc., to very complicated multiple component products such as radios, computers, cars, jet airliners, etc.

All stakeholders would benefit from a clear indication by the DTSC of the types or characteristics of products that are not likely to be identified as priority products. Clarity will allow greater transparency of the DTSC’s decision-making process, while permitting more informed and focused input by stakeholders. Improved understanding of the language and intent of the regulations will encourage responsible entities to better allocate their resources to a limited number of identifiable problems as opposed to committing resources on theoretical concerns. Conversely, lack of clarity will discourage regulated entities from investing resources in green chemistry research and development, forestalling potential widespread public health and environmental benefits.

Recommendation: Improve the clarity of the regulations to indicate the method for prioritization of chemicals of concern. Improve the specificity, criteria, and the standards used in the agency’s decision-making process for prioritization of chemicals or products of concern.

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<sup>3</sup>*Op cit.*

## **The Scope of the Regulation Does Not Match Statutory Authority**

The enabling statute prohibits the DTSC from 1) superseding the regulatory authority of any other federal or State of California agency, 2) duplicating regulations for product categories already regulated or subject to pending regulation or 3) adopting conflicting regulations for such product categories.<sup>4</sup> The purpose of these three separate requirements was to focus the DTSC's resources on protecting consumers and the environment from significant risks posed by consumer products to the extent that such risks are not already adequately mitigated by existing regulations. We do not see any of these three required principles reflected in the proposed regulation.

Also, perhaps of equal concern, are several provisions that seem to contemplate the very actions DTSC is expressly prohibited from taking under the statute. For example, the "End-of-Life" management requirements set forth at §69506.8 mandate a number of additional duties placed upon entities responsible for products that may supersede, duplicate, and/or conflict with existing End-of-Life management requirements. Specifically, many products, such as electronic waste (E-waste), paints, used tires, etc., are subject to existing End-of-Life regulations. It appears that the proposed regulations authorize DTSC to require manufacturers of products subject to existing End-of-Life regulations to develop and fund a separate program which would certainly duplicate, and likely conflict with, the current programs. Many of these products are currently regulated by Cal-Recycle, thus the imposition of such requirements would also clearly supersede Cal-Recycle's regulatory authority.

Another example of entire product categories that are subject to heavy regulation by a myriad of other state and federal agencies are transportation fuels, intermediates used in the production of those transportation fuels, and fuel additives. These product categories are already heavily regulated to address potential impacts to the environment, worker safety, and public health by the California Air Resources Board (ARB), local air pollution control districts, Office of Environmental Health Hazard Assessment (OEHHA), Department of Conservation's Division of Oil, Gas, and Geothermal Resources (DOGGR), U.S. Coast Guard, California Department of Fish and Game, Emergency Management Agency (EMA), State Water Resources Control Board (SWQCB), Regional Water Quality Control Boards (RWQCBs), DTSC, and the U.S. Environmental Protection Agency (USEPA). As you are aware, these agencies monitor and regulate for chemical composition, chemical characteristics, materials handling and disposal, as well as for exposure to ambient and worker environment.

The entirety of federal, state and local regulations demonstrate without dispute, that phases of product life cycles are regulated to protect human health and environment with a high degree of redundancy at both the federal and California state level, the effect of which is to minimize potential risks to human health, safety and the environment. As such, these are the types of categories which we believe H&S Section 25257.1 anticipates should be exempt from the pending Regulations.

We note that previous DTSC regulations also appeared to agree with this interpretation.<sup>5</sup> For example the October, 2011 proposed revisions, Section 69501 (b)(4)(A).1 and (A).2 make that clear:

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<sup>4</sup>Health & Safety Code §§ 25257.1(b) and (c).

<sup>5</sup>As further evidence of the rigorous attention given to fuel regulation in California, your attention is also directed to the September 1, 2010 "Cal/EPA Fuels Guidance Document". It can be found on Cal/EPA's website at <http://www.calepa.ca.gov/biofuels/>. This document provides guidance to the public and regulated community on the scope

*“This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or other California State regulatory program(s), and/or applicable international trade agreements ratified by the United States Senate, that, in combination:*

*1. Address the same adverse public health and environmental impacts and exposure pathways that would otherwise be the basis for the product being listed as a Priority Product; and*

*2. Provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product was listed as a Priority Product. “*

We supported that approach.

Other examples where DTSC actions could be inconsistent with the prohibitions set forth at H&S Code §25257.1(b) and (c) involve the potential imposition of additional Regulatory Response requirements that extend into the workplace, to air emissions, discharges to water or land, waste management, hazardous materials management, or governmental specifications for many types of products, including, but not limited to, military equipment, building materials, vehicle components, fuels, etc. <sup>6</sup>

Recommendation: While the exemption in Article 6 is a step in the right direction, it does not sufficiently incorporate the prohibitions set forth at H&S Code § 25257.1(b) and (c). The proposed regulation improperly places the entire burden upon the responsible party to demonstrate to the DTSC that its actions supersede the authority of another agency, or duplicate and/or conflict with existing or pending regulations.

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and breadth of fuels regulation in California. As indicated at page 4 of this document, the state agencies which contributed to the preparation of this guidance are the primary state agencies involved in the regulation of new fuels in California and which therefore regulate the health, safety and environment for Californians who buy fuels in the marketplace -- the Air Resources Board (ARB), the California Department of Food and Agriculture-Division of Measurement Standards (CDFA), CAL FIRE - Office of the State Fire Marshal (CAL FIRE - OSFM) and the State Water Resources Control Board (SWRCB).

<sup>6</sup>Some commenters at the September 10 hearing expressed concern regarding potential negative impacts to workers and nearby communities associated with perceived regulatory gaps for products manufactured, or stored in California, **but not sold in California** because the DTSC stated the proposed SCPA regulation does not apply to such products. Contrary to those concerns, there are no regulatory gaps for such products because: (1) the federal Occupational Safety and Health Administration and its California counterpart, Cal-OSHA, have jurisdiction over the workplace environment and have numerous existing regulations for the purpose of protecting workers;(2) the California Air Resources Board and the local Air Pollution Control Districts are responsible for regulating air emissions at such facilities for the purpose protecting the local community and environment; (3)the State Water Resources Control Board and Regional Water Quality Control Boards are responsible for regulating discharges to land and water that are also intended to protect the local community and environment;(4) the DTSC and/or local Certified Unified Program Agencies are responsible for hazardous waste management at these locations; and (5) local emergency response authorities typically address the management and storage of hazardous materials at such locations.

Therefore, we strongly recommend that at a minimum the DTSC incorporate the language from §69501(b)(4)(A) of the October 31, 2011 draft informal SCPA regulation as described above.

### **The DTSC Fails to Provide Adequate Protection of Intellectual Property, Confidential Business Information, and Trade Secrets**

The SCPA regulation objective of “benign-by-design” requires that significant investments be made by responsible entities to identify, develop and implement new processes and products, which in-turn necessitates protections for intellectual property, confidential business information and trade secrets. This protection is essential to ensure a return on investment that warrants the risk. Unless the investment in developing this information can be protected with a high degree of certainty, the regulated entity, will direct financial resources to lower risk investment opportunities. Failure to provide certainty with respect to protection of intellectual property, confidential business information and trade secrets will result in less investment in innovation, therefore, slower progress towards achieving the “benign-by-design” objective of SCPA regulation.

We note that this issue remains unaddressed in the current proposed regulations, despite many prior comments from stakeholders who pointed out that failure to adequately protect intellectual property, confidential business information, and trade secrets can imperil the very process DTSC is attempting to encourage. Having to seek trade secret protection remains unreasonably burdensome and whether it will be granted by the DTSC is too uncertain to reliably predict, thus creating a disincentive to invest in developing such information. Specifically, §69510 still requires responsible entities to provide far too much documentation and justification to the DTSC, yet the criteria for granting trade secret protection remains unstated in § 69510.1.

Recommendation: DTSC should focus upon protecting trade secret information and competitively sensitive information. Failure to adequately protect trade secret information in combination with the uncertainty surrounding the amount of discretion retained by the DTSC in its implementation of the SCPA regulation could chill the investment in product innovation and the development, implementation, and adoption of processes by responsible entities that will lead to the design of “safer” products.

### **Warranting Certified Third-Party Assessor is Unnecessary**

As explained in our prior comments upon an earlier version of the proposed regulations, we believe that the use of certified assessors as set forth in Article 8 is unwarranted. Specifically, the reasons offered by the DTSC to reject the status quo, i.e., “no certification”, in its ISOR<sup>7</sup> are inconsistent with the DTSC’s decision to maintain status quo for the first two years that the regulation is implemented –

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<sup>7</sup>See p. 183 of the ISOR. According to the DTSC, adoption of these regulations without including a certification process for assessors would: (1) increase the amount of time required for DTSC’s reviews of the work that is submitted; (2) result in a lack of educational requirements and any person could prepare an AA; (3) result in there being no mechanism to widely disseminate advancements in technologies and manufacturing practices; and (4) result in a lack of consistency in quality and rigor in the preparation of AA. The theoretical negative impacts potentially attributable to these four points will be greatest during the first two years of implementation. However, such impacts should be largely mitigated by the time the certification requirements become applicable; thus, it is unclear why the certification requirements are necessary years after the regulation has been in effect.

precisely the period when both the DTSC and the regulated community are both likely to be least experienced with performing AA Reports. Furthermore, the proposed regulations create a process allowing third-party review and input to the DTSC on the adequacy of both the AA Reports and the proposed Regulatory Response.<sup>8</sup> Third-party review of the AA Reports is afforded via the proposed regulations while the reasons identified as warranting certification of assessors are simultaneously addressed via stakeholder input and DTSC review through the process described at §69506.1(b). Lastly, it is clear that DTSC retains the discretion and obligation to reject inadequate, incomplete, or erroneous AA Reports. This authority makes the requirement of the certified assessor program envisioned by Article 8 unnecessary as well as unduly burdensome.

Recommendation: We recommend the section on certification of assessors be removed because 3<sup>rd</sup> party assessors are unnecessary to assure the accuracy and adequacy of every AA Report, regardless of its complexity. We feel that the DTSC has the capability to ensure that AA Reports are accurate and adequate. Instead of requiring all AA Reports be prepared by certified assessors, we suggest that the DTSC become the principal reviewing authority for AA Reports and related documents, and if some type of additional scrutiny of an occasional complex AA is deemed necessary by the DTSC, it should be the exception, rather than the rule for all AAs. In any event, the DTSC review of AA Reports and all related documents, through whatever process is eventually chosen, must guarantee that intellectual property, confidential business information, and trade secrets are adequately protected.

### **Unclear if the Proposed Regulation Meets All CEQA Requirements**

Many commenters have expressed concern that the proposed SCPA Regulation has failed to satisfy all requirements of the California Environmental Quality Act (CEQA). WSPA shares those concerns as well.

Thank you for your attention. Should you have any questions, feel free to contact me or Mike Wang of my staff ([mike@wspa.org](mailto:mike@wspa.org); cell: 626-590-4905).

Sincerely,



Cc: Mike Wang  
Jeff Sickenger, KP  
Odette Madriago (omadriago@dtsc.ca.gov)

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<sup>8</sup>Specifically, §69501.5(b)(6) states Preliminary AA Reports, Final AA Reports, Abridged AA Reports will be placed upon the DTSC's website where stakeholders may review these documents. Thereafter, stakeholders may offer input to the DTSC on the proposed Regulatory Response, including comments upon the AA Report supporting the proposed Regulatory Response, per §69506.1(b). To the extent that any one or more of the four reasons identified by the DTSC as requiring certified assessors are present in an individual AA report, this process allows the problem(s) to be identified and properly addressed by the DTSC. The additional requirements for the certified assessor program in Article 8 are unnecessary, and therefore, unduly burdensome and wasteful of limited resources.

## GCREgs@DTSC

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**From:** Kristen Wick <kristenwick45@sbcglobal.net>  
**Sent:** Monday, October 01, 2012 12:03 PM  
**To:** GCREgs@DTSC  
**Subject:** Regulations on dangerous chemicals

I strongly urge you to complete and enact strong rules for regulating potentially toxic chemicals. Now that the agency has identified these chemicals, the people of California need and want regulations that will eliminate public exposure to them. The chemical industry cannot be allowed to stand in the way of public health.

Thank you for your prompt attention to this matter.

Kristen C. Wick  




October 11, 2012

Kryisia Von Burg, Regulations Coordinator  
Regulations Section  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, California 95812-0806  
E-mail: gcregs@dtsc.ca.gov  
Fax: (916) 324-1808

Dear Ms. Von Burg:

Re: Proposed California *Safer Consumer Product Regulations*

We prepared these comments based on activities and conversations with our partners and allies in the labor and environmental movements, as well as public and occupational health professionals.

Worksafe is a California-based independent non-profit dedicated to protecting people from job-related injuries, illnesses, and death. We advocate for protective worker health and safety laws and effective remedies for injured workers. In coalition with unions, workers, community, environmental and legal organizations, and scientists, we engage in campaigns to eliminate hazards and toxic chemicals from the workplace. We educate policymakers about the magnitude of workplace hazards and their impact on working people and communities, and propose public health-based solutions that focus on prevention. Many of our activities focus on low-wage immigrant workers and their experiences.

The labor movement and its public, occupational, and environmental health allies have a long-standing concern about the regulation of toxic substances in this country. With worker advocacy organizations like Worksafe, they have been key players in the fight to prevent and reduce work-related hazards and environmental pollution. For many of us, it has evolved into a vision of green jobs that are good for the environment and the people doing the work.

More and more regulatory and policy activities are moving in this direction. Its importance was pointed out in the first-of-its kind September 2012 [report](#) from the United Nations Environment Programme (UNEP). Commenting on

*Global Chemicals Outlook*, UN Under-Secretary General and UNEP Executive Director, Achim Steiner, [explained](#):

*.. the gains that chemicals can provide must not come at the expense of human health and the environment. Pollution and disease related to the unsustainable use, production and disposal of chemicals can, in fact, hinder progress towards key development targets by affecting water supplies, food security, well-being or worker productivity. Reducing hazards and improving chemicals management - at all stages of the supply chain - is, thus, an essential component of the transition to a low carbon, resource efficient and inclusive Green Economy.*

One of the most important global efforts is the Strategic Approach to International Chemicals Management ([SAICM](#)), [endorsed by](#) governments, public health organizations, workers' organizations and the International Labor Organisation (a tripartite -- government, employers, and unions/ workers -- international body). Its work includes the recent important agreements and discussions at the 3rd International Conference on Chemicals Management ([ICCM3](#)). In the context of a life cycle approach, the delegates (including some from the United States):

- reached a consensus decision that endocrine disruptors are a global emerging policy issue and the need for measures contributing to reductions in exposures or the effects of these chemicals, in particular among vulnerable populations;
- added nano materials and electrical and electronic products to the Global Plan of Action; and
- among many things related to electrical/electronic products, prioritized the elimination or substitution of hazardous chemicals, working on tools to help develop designs to reduce and eliminate the use of hazardous chemicals in their production, and tools and information about safer substitutes for chemicals of concern.

Other international efforts to develop innovative prevention-oriented chemicals policies include:

- the [SubSport](#) portal (supporting companies to fulfill substitution requirements of EU legislation);
- the International Chemical Secretariat ([ChemSec](#)) and its Substitute It Now ([SIN](#)) list;
- [Clean Production Action](#), an NGO based in Canada and the United States that has done groundbreaking work with its [Green Screen](#), Red List, and [Healthy Business Strategies for Transforming the Toxic Chemical Economy](#) (showing how companies can plan and design products for better environmental and economic benefits, based on practical experience with a variety of multinationals); and
- chemical policy [plans](#) in China and India that refer explicitly to the progressive European Union's REACH regulation.

In the United States, the federally-funded National Conversation on Public Health and Chemical Exposures developed an [action agenda](#) saying: “(p)romising developments in alternatives analysis and ‘green chemistry’ offer new opportunities for healthier communities, as well as for innovation, greater efficiency, and financial benefit in the marketplace.” It calls on all levels of government to “promote the substitution of hazardous chemicals with less toxic alternatives,” removing policy barriers to the process.

The 2008–2009 [Annual Report of the President's Cancer Panel, Reducing environmental cancer risk. What we can do now](#) is a groundbreaking document prepared by an illustrious group of experts. One of their key points is that we know enough to act on various fronts to prevent and reduce occupational and other environmental cancers. They say that “safer alternatives” to many hazardous chemicals are urgently needed, recommending:

*“Green chemistry” initiatives and research, including process redesign, should be pursued and supported more aggressively, but new products must be well-studied prior to and following their introduction into the environment and stringently regulated to ensure their short- and long-term safety.*

We also have been inspired by [ChemHAT](#), a new chemical hazard and safer alternatives tool being developed by and for workers and the BlueGreen Alliance. The [Alliance](#) includes California-based unions that have been active in developing the electronic tool and other green chemistry/chemical policy activities, with whom we also work on these important issues (e.g., District 9 of the Communication Workers of America -- CWA -- and the United Steelworkers -- USW).

The October 10<sup>th</sup> report, [Counting up to green: Assessing the green economy and its implications for growth and equity](#), from the Economic Policy Institute is based on one released in March 2012 by the Bureau of Labor Statistics ([BLS](#)). The most recent one describes the economics and attributes of a “green economy” that goes beyond energy sector jobs, and does, or could, use tools like ChemHAT. (California has the most green jobs in the country in 2010 -- 338,400.)

The proposed *Safer Consumer Product Regulations* are keeping up with some of these developments and findings, presenting one ingredient in the quest for those green jobs. Yes, they are groundbreaking. More important, they are necessary.

**It is important that workers and workplaces are included in these rules.** First, the authorizing statute requires it. Second, workers and workplaces are found at every stage of a consumer product’s life cycle. Workers extract ingredients for these products, make them, use them, recycle them, and dispose of them. Workers run the water and waste systems that the materials

and their by-products can affect. Workers live in the communities whose air and soil can be contaminated with their ingredients and waste, particularly fence-line communities. As Lisa Cullen said in *A Job to Die For*:

*The workplace is the mother lode of all environmental contaminants and exposures ... Most of what leaches into our drinking water, contaminates our food and pollutes our air comes from workplaces, where it first damages workers.*

We bring that worker/workplace and occupational health lens to the *Regulations*. That is our focus in these comments. Wearing our hats as consumers and citizens, we also care about the environmental health aspects in the proposed rules. However, we expect our allies in environmental health and the environmental justice movement, and other public health advocates and practitioners, will use their particular knowledge of those topics to focus on them in their comments. We support their, and other, efforts to make these *Regulations* the best possible for the sake of California's economy, people, and environments.

Finally, we want to acknowledge our comments are influenced by the inspiration and leadership about occupational and environmental health provided by Barry Commoner, who died recently. Promoting integrated views of the world, one of his important contributions for the purposes of these comments comes from *The Closing Circle* (1971). It is the notion that corporations, government, and consumers need to be in sync with the "four laws of ecology":

- ✓ *Everything is connected to everything else.*
- ✓ *Everything must go somewhere.*
- ✓ *Nature knows best.*
- ✓ *There is no such thing as a free lunch.*

These four "laws" are key to healthy and green economies, communities, and workplaces. They underlie the *Regulations'* life cycle approach and its public health goals.

With this framework, our comments are divided into general and specific sections. They are in the attached document. Please let me know if you have questions about any of them.

Sincerely

A handwritten signature in cursive script that reads "Dorothy Wigmore".

Dorothy Wigmore, M.S.  
Occupational health specialist



## **Comments about the proposed California *Safer Consumer Product Regulations***

### **General comments**

These *Regulations* are needed. They are an important, and ground-breaking, first step towards a state with fewer toxic substances and healthier, greener and more economically-sustainable communities.

For the first time, consumer product manufacturers must formally answer a key question about their practices: "Is the use of this hazardous chemical necessary in my product?" The original statute says they must focus on inherent hazards in those products and their ingredients, not a risk assessment of individual chemicals. This also is the first time that chemical regulations in this country try to account for cumulative exposures, a key occupational/public health concern and long-standing demand from environmental justice communities. And this is the first time a U.S. agency has tried to build a comprehensive regulatory structure that combines these approaches with requirements that manufacturers look for less toxic or non-toxic alternatives.

Like many of those concerned about the level of toxics in our lives, we urge DTSC to publish the final version of the *Regulations* as soon as possible, and start the process required in AB 1879. These regulations have gone through enough iterations. They are not perfect -- far from it. However, it's time to "get on with it" and see how they work. It has taken far too long to initiate these important steps to reduce the toll of toxic substances in the state and to show the rest of the country, and the world, how California can once again be a leader of important public policies.

We also urge the governor and California state legislators to show leadership by supporting these regulations and the programs related to them in several ways. It should be their top priority to ensure that DTSC has the funding needed to implement this program effectively. Everyone involved agrees the Department does not have the resources required now; in fact, it has cut back on other pollution prevention activities to focus on this part of the Green Chemistry Initiative (GCI).

We also support the CHANGE coalition's consistent feedback about the current paucity of information about the individual and combined effects of many of the 85,000 or so chemicals in commerce in the U.S. Paraphrasing their comments, we support a "no data, no market" requirement to close the

pervasive data gaps. This will level the playing field for all chemicals and the companies that make, import, and use them.

The proposed program limits DTSC's ability to require a minimum data set for all chemicals in commerce. This is a key shortcoming. Without comprehensive toxicity information, the Department's job is much more difficult than it should be. Therefore, building a "no data, no market" mechanism into California's regulatory structure is another key task for the legislature. We need laws, and related regulations and policies, to fill the data gaps outlined in the 2006 report to the legislature "*Green chemistry in California: A framework for leadership in chemicals policy and innovation*".

The questions "*Is this toxic substance necessary?*" and "*Is there a 'safer' alternative with no or limited health or environmental effects?*" are particularly important to us, given limited information about the toxicity of so many chemicals produced and/or used in California. They need to be asked about possible alternatives too, to avoid regrettable substitution.

We are pleased that some companies are taking these questions seriously and innovating their products and processes in the move towards a "green economy." Unfortunately, other industry voices have chosen the opposite response. They are calling for delays while raising inaccurate and exaggerated predictions about economic effects and cumbersome processes.

Those with long memories and historical views recognize the patterns. As EPA chief, Lisa Jackson, said in 2010:

*Today's forecasts of economic doom are nearly identical -- almost word for word -- to the doomsday predictions of the last 40 years. This "broken record" continues despite the fact that history has proven the doomsayers wrong again and again. ("Feeling heat on climate, EPA celebrates its past", [New York Times](#))*

Studies and reports that document her point -- and the possibilities that result from regulatory initiatives -- include:

- the Natural Resources Defense Council's recent analysis showing the "[delay game](#)" industry has played in response to EPA health assessments and regulation of chemicals;
- economic analyses of environmental and occupational health regulation, such as [Not too costly after all: An examination of the inflated cost estimates of health, safety and environmental protections](#), and [Setting the record straight: The Crain and Crain report on regulatory costs](#);
- the ground-breaking 2011 [report](#) showing we need regulations to protect people and the environment, and the improvements they provide;
- [examples](#) of the business case for policies like these *Regulations*, from the federal Occupational Health and Safety Administration (OSHA) ; and
- Worksafe's [Prevention pays](#).

Efforts to derail and dilute the proposed *Regulations* ignore the urgent need to reform the regulation and use of chemicals in California, and what is happening in the rest of the world (where many of the large companies complaining about the *Regulations* operate). They ignore the true costs of the current approaches that allow people, communities, and their environments to be guinea pigs for untested chemicals and the products in which they are found.

The *San Francisco Chronicle* editorial of September 30, 2012 made the correct point:

*Now, despite bipartisan support from lawmakers (for the 2008 authorizing statute), the pact is in danger of unraveling at the hands of the powerful chemical industry, which is lobbying every state official it can corner. To dilute this legal protection would be a disservice to California consumers.*

*... The (DTSC) needs to hear, emphatically, that these (potentially toxic) chemicals must be regulated and removed, and the **chemical industry can't be allowed to stand in the way of public health** (emphasis added).*

We agree and want to emphasize the importance of prevention and solution-focused policies and activities, especially for businesses:

*It is better to put a fence at the top of a cliff than an ambulance at the bottom. Companies are so bottom-line driven, prevention can be a hard sell, but it is always a better solution. (Director of Corporate Health Solutions for a Gary, Indiana hospital, *Indiana Business Magazine*, 2004)*

## **Specific comments**

We divided this section of our comments into what we support in formal version of the *Regulations* and where there are opportunities for improvements.

### **A. The *Regulations* are headed in the right direction**

We are pleased that occupational health is rightfully acknowledged as a public health issue in the proposed *Regulations*. This is consistent with the original statute, the life cycle approach it laid out, and the definition, understanding, and practice of “public health.” It also is important to include workers and workplaces as they are sometimes invisible players in this important effort. They are key at all stages in the life cycle of consumer products, including use, and often have higher exposures than most other consumers.

We also are glad to see that the *Regulations*:

- ✓ are part of the GCI, a broader and integrated effort to reduce the presence of toxic substances in the state and their effects on the environment, the public, and workers;
- ✓ are somewhat consistent with a green chemistry approach, at least emphasizing the inherent hazards of chemicals rather than the “risks” or odds they will have an effect, so that manufacturers are expected to develop products that are non- or less toxic (i.e., primary public health principles);
- ✓ use a life cycle approach that is a crucial framework for any modern and effective chemicals policy effort;
- ✓ advance chemicals policy activities by looking beyond individual chemicals to the cumulative effects they have with other chemicals, and to examining the hazards of the products in which they are used (which we want to ensure is expanded to include other factors);
- ✓ propose a realistic, unranked list of “chemicals of concern” based on lists that have made it through the prioritization processes of reputable scientific bodies and legislative authorities, covering many of the “hazard traits” of concern to workers and their employers (also see our recommendations for additions);
- ✓ define “sensitive subpopulations” to include “a meaningful portion of the general population that are identifiable as being at greater risk of adverse health effects when exposed to one or more chemicals that exhibit a hazard trait or toxicological endpoint”, with recognition of workers as a group that has higher exposures (see our suggestion for the latter part, below);
- ✓ allow a realistic case-by-case approach to determine the amount of a chemical of concern in a product at which the Department will set a threshold point for regulatory action;
- ✓ include “places of employment” (i.e., workplaces) in the definition of reliable information about monitoring that shows there are exposures to chemicals (provided it meets a better definition of “reliable information,” as explained below);
- ✓ requires that those accrediting alternatives assessors understand occupational health issues, with some specifics; and
- ✓ have explicit language that health, safety, and environmental information or chemical identity cannot be a trade secret in hazard trait submissions (although we do not support the exception for proposed alternatives).

We have three recommendations to make these positive steps more effective.

**Recommendations:**

Update the chemicals of concern list every two years, as opposed to “periodically.”

Ensure the trade secret claims process is as transparent as possible; review the provisions in the Cal/OSHA *Hazard Communication Standard* ([http://www.dir.ca.gov/dosh/dosh\\_publications/hazcom.pdf](http://www.dir.ca.gov/dosh/dosh_publications/hazcom.pdf)) to avoid undermining those provisions. (We also support the more detailed CHANGE comments about this topic.)

Work with Cal/OSHA and the Department of Public Health's Occupational Health Branch (CDPH/OHB) to integrate efforts to protect workers and provide healthier workplaces. Reflect these results in guidance documents and related materials.

## **B. Opportunities for improvements**

We see opportunities for various improvements that are consistent with AB 1879 and a comprehensive framework to meet its goals. All our points are in this document, except for those about the alternatives assessment reporting process. We support CHANGE's position about the lack of transparency and oversight, key flaws in the proposed *Regulations*.

### **1. Make workers and workplaces more visible**

Overall, workers still are relatively invisible in the proposed *Regulations*. The name is used only twice and "workplace" is used once [besides the expectations about occupational health knowledge in s. 69508.1(a) (5)(G) (page 69, lines 10 – 11)]. Similarly, "occupation" or "occupational" turn up a total of four times, including the definition referred to in the cited lines.

As we said in an earlier letter, also signed by the California Labor Federation, the California Construction and Building Trades Council, and the District 9 director of the Communication Workers of America (CWA):

*Without more direct and clear language, workers and employers will be poorly informed about their rights and responsibilities related to the regulations and alternatives assessors may not account for occupational exposures.*

Whether or not the Department makes workers and workplaces more visible using our proposed language, they need to issue mandatory appendices or guidance documents explaining how workplaces/places of employment are expected to deal with these regulations. The documents should be prepared in a way that differentiates places where the products are manufactured from those where they are used, disposed of, recycled, or re-purposed. Occupational health and workplace considerations also need to be clearly stated for those doing alternatives assessments and Department staff overseeing submissions under these *Regulations*.

### **Recommendations:**

Emphasize the inclusion of occupational health and workplaces by:

- adding “(including occupational health)” to sections where DTSC and others must consider public health [e.g., after “public health” in S. 69502.2(b)(1)(C), page 23, line 34];
- adding “(including workers)” where DTSC and others must consider sensitive subpopulations [e.g., after “sensitive subpopulations” in S. 69502.2(b)(1)(B) 1, page 23, line 28];
- explicitly state that “adverse air quality impacts” include indoor air quality [s. 69501.1(a)(3), page 4, lines 37 - 39]; and
- define “consumer product” to be clear that it includes chemicals and products used on the job, including bulk purchases [s. 69501.1(a)(22)(A), page 8, line 32].

For information about how mandatory appendices can be used to accomplish this, see the Cal/OSHA [Hazard Communication Standard](#).

The broad definition of sensitive subpopulations [s. 69501.1(a)(58)] recognizes that occupational hazards often lead to greater exposures than those encountered in other settings (e.g., someone cleaning their own home). The exposures can be both higher and more frequent, making the hazard significant.

The wording is problematic, in that it is not the “nature of their occupation” but the job tasks or activities that are important. For example, studies show that female cleaners and parks workers face different ergonomic and chemical hazards than their male counterparts, even when they have the same job title. What they really do is what matters.

The definition also should be expanded to include women and men of reproductive age. Traditionally, women of child-bearing age are considered to be a sensitive sub-population. Unfortunately, this ignores long-time evidence that men’s occupational and environmental exposures (e.g., to lead, solvents, DES) affect their ability to conceive and have healthy children.

**Recommendations:**

Change the last phrase in this definition [S. 69501.1(a)(58), Page 13, lines 19 - 25] to read: “ .. greater exposures, or workers with greater exposures than other people, due to the nature of their occupation, accounting for tasks or activities”.

Add “women and men of child-bearing age” to the definition.

There are 12 elements in the end-of-life management plan. Responsible entities are expected to develop a plan that includes “the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse multimedia impacts.” Occupational health needs to be specifically mentioned here, as we and others have recommended.

## **Recommendation:**

Reword to read “.. the steps that will be taken to ensure compliance with all applicable federal and California State and local laws, and that addresses any adverse occupational health and multimedia environmental impacts.”

## **2. Don't exclude products made in California but not sold in the state**

Inclusion of s. 69501(b)(3) continues to perplex us. There are many arguments about why it should not be there. We present a few.

Workers are present at each stage of a chemical or product's life cycle. For most product uses, therefore, workers face higher and more intensive exposures than the general public. For example, the estimated 73,637 tons of general purpose cleaning products sold every day in California are used occasionally by household consumers, but daily by workers. Many workers face daily hazards from commercial products sold to consumers, such as paint thinners, solvent products, degreasers, paint strippers, carpet cleaners, and maintenance products. Workers involved in manufacturing these chemicals often face the most intense danger of all.

A life cycle approach includes the manufacture of products in California, regardless of where those products are eventually sold. As such, the *Regulations* should apply to all products manufactured in, stored in or transported through California, whether the products are sold here or not. The statute does not require this section. An upstream approach that captures products made in, stored in, or transported through the state is consistent with the GCI and the goals of AB 1879.

Other reasons to exclude this section include:

- Making products almost always contaminates the environment in some way, whether it is air, water, or land, unless pollution prevention strategies like these regulations are used. Otherwise, it is an invitation to more environmental contamination in the state, contrary to the rationale for the *Regulations*.
- It is unethical, as it effectively says you can make toxic products here or elsewhere, or ship them through the state, as long as you don't actually sell them in California.
- It is an economic disadvantage to companies making consumer products in California that send them out of the state, as well as sell them inside it.
- The rationale for this section in the *Statement of Reasons* refers to s. 25251, which defines several things, including a consumer product. That section does not refer to where the product is made or transported, nor does it exclude these activities as they involve products. The Department is inferring an intent for which there is no evidence in the enabling statute or the referenced documents.

- AB 1879 says the process in the regulations must consider at least three things, one of which is the potential for exposure to a consumer product’s chemicals. It does not say when this exposure must take place, again not excluding manufacturing, transportation, etc.
- It is unfair to put the onus on those providing comments about these regulations to find examples to back up concerns about this exclusion. As DTSC knows, it is extremely difficult to find up-to-date and accurate information about the range of chemicals and products produced, exported, and transported through this state. We have tried, without success so far. This is not surprising. A 2003 [analysis](#) by the Hazard Evaluation System and Information Service in the Department of Public Health (HESIS) found there are no tracking systems for chemicals or their products in California. CDPH/OHB currently cannot require manufacturers of a particularly toxic substance to reveal manufacturing locations so that workers can be warned of new hazard information about a chemical (e.g., diacetyl). (In 2005, AB 816 proposed this process; unfortunately, it was vetoed.)

Finally, this section is inconsistent with other parts of the *Regulations*. For example:

- “life cycle” is defined to include manufacture, transport and distribution [s. 69501.1 (a)(39)];
- the DTSC product prioritization process must consider the adverse effects of exposures during a product’s life cycle [s. 69503.2 (a) (1)];
- the same process refers to exposures during the life cycle, specifically naming “(m)anufacturing, use, storage, transportation, waste, and end-of-life management practices and the locations of these practices” [s. 69503.2(a)(B)4.a]; and
- relevant factors in the second stage of alternatives analysis include those during the life cycle that make “a demonstrable contribution to one or more adverse .. impacts”, including occupational health [s. 69505.4(a)(1)(A)1].

**Recommendation:**

Delete s. 69501(b)(3).

**3. Expand the chemicals of concern list to include other serious hazard traits affecting consumers and workers alike**

More than 85,000 chemicals are currently available in the United States. However, the “list of lists” of “chemicals of concern” captures only a small portion of these mostly-untested substances. DTSC should augment the list with asthmagens, respiratory sensitizers, skin irritants, and skin sensitizers, all of which are already in the list of hazard traits in Chapter 54. These substances pose serious adverse effects for workers and consumers alike.

For example, a recent report for the National Institutes of Health, [Healthy environments. A compilation of substances linked to asthma](#), found 374 substances linked to asthma are used or present in buildings. A substantial number are found in products; 75 alone are in paints and adhesives, both of which are consumer products used in homes and other buildings.

Asthmagens take an expensive toll on individuals and society, including children. Asthma is the fourth leading cause of work absenteeism, costing almost “12 million missed or less productive workdays each year.” People with work-exacerbated asthma (WEA) report more days with symptoms, go for more medical care, and have a lower quality of life compared to adults with asthma unrelated to their job(s) ([American Thoracic Society](#), 2011). In Massachusetts, WEA cases are most commonly linked with cleaning products (13.2%); most of the hazard sources are either consumer products or common ingredients in them ([Asthma](#), Massachusetts Toxics Use Reduction Institute TUR and disease prevention fact sheet, 2012).

The 2010 report, [Asthma: A Business Case for Employers and Health Care Purchasers](#) advocates for replacing of “harsh cleaning chemicals” and other hazards. So too do California scientists, public health researchers and state public health officials (e.g., “[Primary prevention of occupational asthma: Identifying and controlling exposures to asthma-causing agents](#)” by Dr. Julia Quint and others, the state public health department’s [Strategic Plan for Asthma in California 2008 – 2012](#), and the [CDPH/OHB](#)). The American Thoracic Society agrees with them in its [official statement](#) about WEA.

Other respiratory sensitizers, skin sensitizers, and skin irritants also cause adverse public/occupational health effects that make people’s lives miserable and are expensive for employers, workers, their families and their communities. These hazard traits are common in workplaces and other consumer settings.

The National Institute for Occupational Safety and Health (NIOSH) estimates that more than 13 million U.S. workers can be exposed to chemicals absorbed through the skin. These [hazards](#) lead to skin diseases and allergies, and systemic effects ranging from acute effects and neurotoxicity to cancers and reproductive health effects. Again, the results are very expensive; estimated total annual costs are up to \$1 billion in 2002. The non-occupational burden of skin diseases increases the costs to society (not the manufacturer), even when the sources are limited to consumer products.

There are reliable lists for substances with these hazard traits from North American and European sources. As part of implementing the Globally Harmonized System of Classification and Labeling of Chemicals ([GHS](#)), the U.S. federal [Hazard Communication Standard](#) soon will require these hazard traits be named on “safety data sheets.” Other jurisdictions and organizations already recognize their importance.

**Recommendation:**

Expand the list of chemicals of concern to include asthmagens, respiratory sensitizers, skin irritants, and skin sensitizers. See Appendix 1 for our list of recommended sources. Note that most are ones that DTSC already plans to use for other purposes [e.g., s. 69502.2(a)(1)(B)].

**4. Change the language about causation**

DTSC has chosen to move away from AB 1879's use of "potential" hazards, exposure, and effects on sensitive sub-populations [see sections 25252 (a)(2), 25252 (a)(3), 25253(a)(2) and 25253 (a)(2)(K)], although the use of "potential" is legally defensible and should be binding. In fact, we question the legality of making this change.

Using the word "ability" puts an excessive onus on DTSC to show that chemicals and products cause harm to people and/or the environment. Given how quantitative epidemiological studies and chemical tests are conducted and interpreted, scientists and researchers interpret "cause" very conservatively. Epidemiologists traditionally want to be 95% sure they are correct, a level of proof far above that required in other arenas, including legal ones. Furthermore, they will argue until the cows come home about what is a "significant ability to contribute to or cause" a particular effect. This leads to fruitless arguments that have little to do with preventing and reducing the use of toxic substances.

Hence, it is important to retain the phrase "potential" to retain the GCI goals .

**Recommendations:**

Drop use of "cause" and replace with "potential" in the priority products prioritization factors [sections 69503.2(a)(1)(A) 1 - 3; page 25 line 32 and page 26, lines 7 and 16].

In s. 69503.2(b) 1 (page 27, line 27), replace "significant ability to contribute to or cause ..." with "the Chemical(s) of Concern in the product has the potential to contribute to or cause adverse...".

In s. 69503.2(b) 2 (page 27, line 31), replace "significant ability for .. to be exposed to the Chemical(s) of concern in the product in quantities that would contribute to or cause ..." with "ability for the ... to be exposed to the Chemical(s) of concern in the product in quantities that have the potential to contribute to or cause ...".

Elsewhere, use "reasonable likelihood to cause or contribute" or "reasonably likely to," instead of "ability to cause or contribute."

## 5. Re-consider the definition of reliable information

There is increasing evidence that single published papers may not be “reliable information.” This is particularly true of those sponsored by industrial or commercial concerns, as [UCSF researchers](#) and others have shown.

Single studies or case reports can point to the “canaries” (i.e., early warning signs or clues) of possible hazards, and help researchers, practitioners, and worker representatives make sense of their personal experiences, leading to further investigations. However, one published study with negative or very inconclusive results should not be grounds for discounting a chemical’s hazards. The biases reported in industry-sponsored or financed studies also need to be taken into account in any criteria about “reliable information” being used for public policy.

### **Recommendation:**

Consult with the UCSF researchers about how their findings in the [study](#) can provide a better definition of reliable information, one that accounts for industry bias and considers when a single study should be used.

## 6. Expand the factors considered in “cumulative effects”

We strongly support the use of cumulative effects in the *Regulations*. It is an important step to understand and account for the effects of chemicals. People are not simple slots into which one can put a chemical and understand its effects, without accounting for everything from the ergonomics of their activities, the temperature of their environment, and the hours they work, to gender, where they live, the food they can afford, and how they get around. For a simple example, we know that organic solvents increase the [hearing loss](#) of those in noisy environments.

More and more prevention-oriented efforts are trying to deal with the real-life integrated effect of specific chemicals, other hazards, and environmental surroundings (e.g., see the work of the Canadian Partnership Against Cancer, [www.partnershipagainstcancer.ca](http://www.partnershipagainstcancer.ca)). The [European Commission](#) is developing new approaches, and some California EPA activities, in particular the tools developed by OEHHA’s Cumulative Impacts and Precautionary Approaches Workgroup, show great promise. (DTSC should maintain its commitment to those efforts.)

### **Recommendations:**

Expand how cumulative effects are understood and considered to go beyond “other chemicals with the same or similar hazard traits.” Use language that commits DTSC also to consider other environmental

factors, such as, but not limited to, the built environment, socio-economic status, and nutrition.

For the best assessment possible, allow this to be done using qualitative and mixed quantitative-qualitative analysis.

## **7. Take a more preventive, public health approach to alternatives**

The proposed *Regulations* are supposed to be part of the state's GCI. Yet one overwhelming impression after reading them is the emphasis on containing or controlling exposures, not preventing the use of toxic substances in products. The latter is the most effective means to deal with a hazard, and the primary public health approach.

Containing and controlling are much less effective measures. Some of them (especially those that count on individual actions such as wearing protective clothing or following instructions about "correct" use) clearly only limit harm and do little to prevent adverse environmental or human health effects. (See Appendix 2 for a prevention triangle that summarizes this principle, based on the Belgian occupational health law.)

We fully support the hazard-based starting point of green chemistry and the proposed *Regulations*. We support the use of language such as giving "preference to regulatory responses providing the greatest level of inherent protection" [s. 69506(b), page 52, lines 10 -14].

We urge DTSC to use that starting point as the framework for its assessments and decision-making, and to put into practice the public health tenets of recognizing that controls or containment are interim and less effective solutions.

### **Recommendations:**

Rather than describing the process as considering alternatives to priority products to determine "how best to limit exposure to" a chemical of concern, explicitly state that it is about determining "how best to reduce the use of toxic chemicals" [s. 69501(a), page 4, lines 8 - 12].

Where there is talk of reducing exposures and effects, explicitly state that the goal is removal of toxic substances, re-design of processes, etc., and that other measures are less effective steps that may be necessary on an interim or short-term basis.

Use the prevention triangle in Appendix 2 as one tool in guidance, and related documents to explain the principles and goals.

## 8. Expand the definition of costs

In the second stage of alternatives analysis, s. 69505.4(1)(C) [page 43, lines 28 - 41], the current version of the *Regulations* tells responsible entities to “take into account all projected direct and indirect cost impacts during the life cycle of the product and the alternatives being considered.” Yet it defines a cost impact as an increase or decrease in a way that is contrary to the authorizing statute. It does not list indirect costs that are part of “the overall costs of those impacts to the state’s society” [s. 25255(2a) of AB 1879].

We are most familiar with studies about the costs of occupational illnesses and diseases. (There are similar studies about illnesses and diseases linked to environmental health and community health; again, we leave it to our environmental health colleagues and allies to provide that information.) These studies are few and far between, since most discussions center on what solutions cost, rather than what the “problem” -- the hazard and its effects -- costs.

These expenses often are externalized -- essentially given to individual workers, their families, communities and government agencies and (in the US) insurance companies that must deal with the wide array of personal, medical, and social costs attributable to occupational hazards. For example, UC Davis’ Paul [Leigh](#) reported in 2011 that:

*... medical and indirect costs of occupational injuries and illnesses are sizable, at least as large as the cost of cancer. Workers’ compensation covers less than 25 percent of these costs, so all members of society share the burden.*

Even leaving out important illnesses and diseases that could be related to chemical exposures, he found the USA’s [economic burden of occupational injury and illness](#) to be 516,149 deaths and cases that cost an estimated \$20.83 billion in 2007. Chemicals are a sizeable portion of occupational hazards, on their own or in combination with other hazards, and therefore of Leigh’s estimates.

### **Recommendations:**

Return to the original statute’s intention of “overall costs.”

Expand the definition of costs to include the externalized ones that others must pay during the life cycle of the product and its alternatives.

Include “occupational health and safety protection costs associated with use of the product.”

## 9. Recognize that monitoring data is hard to come by

Lists that form the basis of the “chemicals of concern” are changed on different timetables than studies and other reliable sources of information.

The reasons may also differ from those behind the proposed *Regulations*. Therefore, it is appropriate that DTSC have the responsibility, and ability, to identify other substances that should be on the chemicals of concern list.

Several criteria about updating lists [s. 69502.2(b)] are relevant to workers and occupational health practitioners: “sensitive subpopulations,” the ability to “contribute to or cause widespread” adverse public and/or environmental health effects, and exposure information.

Unfortunately, the exposure criteria may be difficult to apply. There is remarkably little accurate information available about what is sold and used in California homes, workplaces, and communities. There is even less monitoring of exposures. Monitoring methods have a history of being misused (e.g., area sampling applied to personal exposures) and the results misinterpreted. Therefore, “widespread” may be difficult to determine.

However, some occupational health regulations and enforcement activities require employers or Cal/OSHA inspectors to monitor for workplace hazards; in the latter case, the employers should have the results. Some employers include monitoring of hazards in their injury and illness prevention programs and other occupational health activities. This information could be used in efforts related to these *Regulations*.

#### **Recommendations:**

Keep s. 69502.2(b) as is, provided the definition of “reliable information” is clarified, and the (illegal?) use of “cause” instead of “potential” is dealt with (see above).

Establish a transparent balancing of the lack of exposure information and need for details about exposure monitoring methods and results (to assess how relevant, accurate, and reliable they are) with the understanding of “widespread.”

Have transparent criteria for “widespread”. Use that criteria elsewhere in the *Regulations* [e.g., s. 69503.2(a)(1)(A)3].

Require responsible entities to submit information from relevant occupational hazard monitoring, including chemical names, number of workers and others exposed to the hazard, results and responses to the results. Work with Cal/OSHA to determine what information should be available, from whom, and how it could be used. Provide appropriate guidance based on the results.

#### **10. Be cautious about the use of occupational exposure limits**

Section 69501.1(a)(6) (page 6, lines 4 - 5) talks about “exceedance of an enforceable .. standard relating to the protection of public health.” When applying this definition, DTSC should not include the standards known as occupational exposure limits (PELS or Permissible Exposure Limits in the

U.S.). They are out-of-date in terms of current toxicological information. Many offer “protection” for acute effects only, and the illusion that chronic effects are considered. And all too often, workers have symptoms and suffer acute and chronic effects when exposed to levels below these standards.

For example, in 2007 the state Office of Environmental Health Hazard Assessment (OEHHA) and the CDPH/OHB HESIS program looked at chemicals known to cause cancer or reproductive harm under Proposition 65. [More than 100](#) had no workplace permissible exposure limits (PELs) to protect workers from those effects. Most federal OSHA PELs have not been [updated](#) since 1971.

**Recommendation:**

In materials describing “adverse public health effects”, make clear that occupational exposure limits (OELs), and U.S. PELs in particular, are not enforceable standards that protect public health. Otherwise, deliberately exclude PELs and other OELs from the standards that are related to public health.

**11. Expand what DTSC considers in its regulatory responses**

Section 69506(c) sets out the principles for the department’s regulatory responses. We support having these in the *Regulations*, and recommend one addition that is in line with protecting public health and the environment.

As we and others advocated in a June 2012 letter, “just transition” should be a factor in regulatory responses. This idea came from Tony Mazzocchi, a union leader and early environmentalist. Inspired by the GI Bill (*The Servicemen’s Readjustment Act of 1944*), he called for a GI Bill for workers and their (often fence-line) communities. When they lose jobs thanks to the sunset of hazardous industries or substances, he wanted a “just transition” so they were not abandoned. They could be supported financially to learn and use new skills, particularly in green jobs in a green economy. The idea has been taken up by others (e.g., see the 2010 ILO report, [Climate change and labour: the need for a “just transition”](#)).

**Recommendation:**

Add consideration of a “just transition” to the regulatory response analysis: “The impact on communities (e.g., neighbors, employees, suppliers) connected to the manufacture of a product and ways to mitigate anticipated adverse impacts on those communities.”

**12. Ensure that public information includes “safety data sheets”**

The GHS (Globally Harmonized System) is changing how manufacturers present information about their products. Material safety data sheets

(MSDSs) will be called “safety data sheets” (SDSs). Currently, MSDSs are available for consumer products in some jurisdictions and often when those products are used in workplaces. (It is one requirement about providing information, set out in *Hazard Communication Standard* from the federal Occupational Safety and Health Administration -- OSHA -- and its California equivalent, Cal/OSHA.)

Sections 69505.5(e) (page 46, starting at line 35) and 69506.4 (page 54, starting at line 11) refer to information that should be provided. MSDSs or SDSs should be added, to be consistent with other state regulations and take advantage of existing information.

**Recommendation:**

Add “material safety data sheets (MSDSs) or safety data sheets (SDSs)” to the lists of information that must be provided.

**13. Make materials available in languages other than English**

The requirements in S. 69501.5 [page 19, lines 1 - 42; and page 20, lines 1 - 38] will enhance workers’ right to know about the hazards of products they use, and the Injury and Illness Prevention Programs ([IIPPs](#)) their employers must prepare to meet Cal/OSHA regulations.

Unfortunately, the information will be available only in English. This does little for the many people in the state with literacy issues in that language. The lists of chemicals of concern and priority products should be available in Spanish and other relevant languages. This also will assist retailers and other users. Other state government agencies already do this (e.g., Cal/OSHA, DLSE).

**Recommendation:**

Post information in Spanish when possible, and definitely when it is available in that language. Publish the lists of chemicals of concern and priority products in Spanish.

## Appendix 1

For asthmagens, skin irritants, and other sensitizers, see:

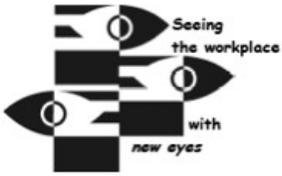
- <http://www.cdc.gov/niosh/topics/skin> (NIOSH information about skin irritants and sensitizers);
- <http://www.aoecdata.org/ExpCodeLookup.aspx> (Association of Occupational and Environmental Clinics -- AOEC);
- European Union EC 1272/2008 Annex VI: (1) Category 1 respiratory sensitizers; (2) Category 1 skin sensitizers:  
<http://esis.jrc.ec.europa.eu/index.php?PGM=cla> (*European Chemical Substance Information System*. Table 3.1, searching for H317 Skin sensitizer Cat 1 -- may cause an allergic skin reaction -- and H334 Respiratory sensitizer Cat 1 -- may cause allergy or asthma symptoms or breathing difficulties if inhaled.);
- [http://www.cleanproduction.org/library/greenScreenv1-2/Green Screen v1-2 Supporting Lists.pdf](http://www.cleanproduction.org/library/greenScreenv1-2/Green%20Screen%20v1-2%20Supporting%20Lists.pdf) and search within for
  - 67 EU H-statement, H317 "May cause an allergic skin reaction",
  - 75 EU H-statement H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled",
  - 120 EU R-phrases R42 "May cause sensitization by inhalation",
  - 121 EU R-phrases R43 "May cause sensitization by skin contact",
  - 169 MAK Sensitizing Substances Sa (Respiratory),
  - 170 MAK Sensitizing Substances Sh (Skin),
  - 236 GHS-[COUNTRY] Category 1A (High Frequency of Occurrence), and
  - 237 GHS-[COUNTRY] Category 1B (Low to Moderate Frequency of Occurrence);
- National Institute for Occupational Safety and Health's 2009 *A strategy for assigning new NIOSH skin notations* (*Current Intelligence Bulletin 61*), and the chemicals which they have evaluated using this strategy ([http://www.cdc.gov/niosh/topics/skin/skin-notation\\_profiles.html](http://www.cdc.gov/niosh/topics/skin/skin-notation_profiles.html))
- EU *Dangerous Substances Directive* (67/548/EEC), being replaced June 1, 2015 by GHS-related *Regulation (EC) No 1272/2008 - classification, labelling and packaging of substances and mixtures* (with current phrases): R21: Harmful in contact with skin; R24: Toxic in contact with skin; R27: Very toxic in contact with skin; R38: Irritating to skin; R43: May cause sensitization by skin contact; R66: Repeated exposure may cause skin dryness or cracking; S24: Avoid contact with skin; S28: After contact with skin, wash immediately with plenty of ...(to be specified by manufacturer) (see <http://osha.europa.eu/en/legislation/directives/exposure-to-chemical-agents-and-chemical-safety/osh-related-aspects/regulation->

[ec-no-1272-2008-classification-labelling-and-packaging-of-substances-and-mixtures](#))

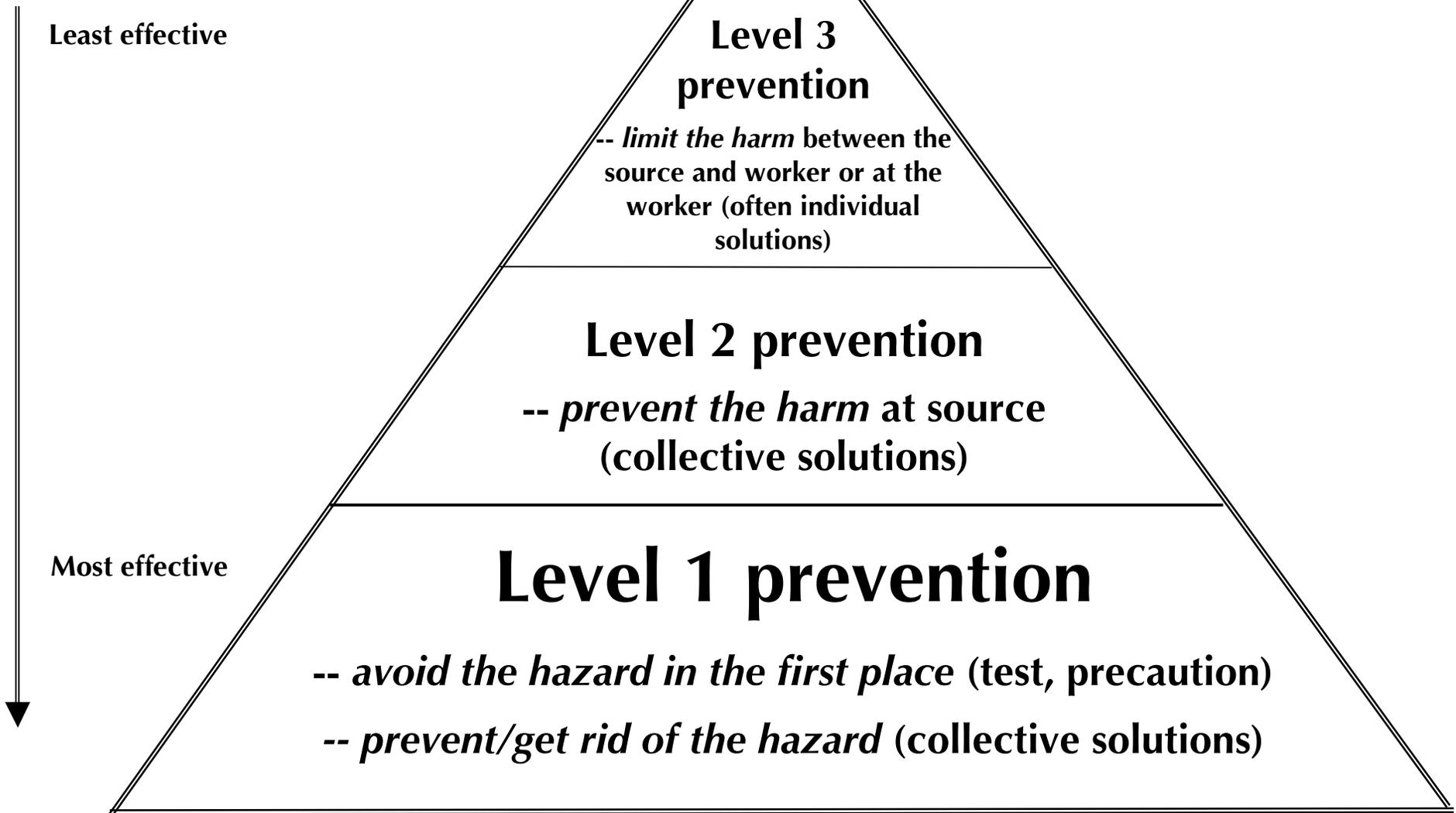
For other additions relevant to occupational and other settings, see Julia Quint's earlier recommendations:

- European Chemicals Agency *Candidate List of Substances of Very High Concern*  
([http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp));
- US EPA TSCA S. 5(e) *Existing Chemical Substance Significant New Use Regulation* (SNURs)  
(<http://www.epa.gov/oppt/existingchemicals/pubs/sect5a2.html>);
- US EPA *Existing Chemicals Action Plans*, chemicals for which EPA has developed plans (<http://www.epa.gov/oppt/existingchemicals/>);  
and
- US EPA TSCA S. 8(e) submissions  
(<http://www.epa.gov/oppt/tsca8e/pubs/8emonthlyreports/2011/8ejan2011.html>).

## **Appendix 2 -- The prevention triangle**



# The prevention triangle -- *principles for solving health and safety problems*



\* *What happens if it's upside down (and you just limit the harm)? It falls over!*

# *What's behind the prevention triangle?*

The triangle borrows two concepts from the environmental movement.

**Informed substitution** is the principle about getting rid of toxic substances whenever a healthier and/or safer substance is available. Replacements are non-toxic or much less hazardous materials. It also describes changes about how things are done, using a different technology or re-organising the task to reduce or get rid of hazards. For more, see [www.cleanproduction.org](http://www.cleanproduction.org) and [www.turi.org](http://www.turi.org).

The **precautionary principle** -- "better safe than sorry" -- is part of several environment and health and safety laws. The idea is that there must be proof that something is not harmful before it is used, rather than using workers or the community as guinea pigs and only taking action when problems appear. For more information, see the European Environment Agency's <http://latelessons.ew.eea.europa.eu/>.

Health and safety specialists have used the word "controls" to describe changes or solutions that reduce exposure but don't get rid of the hazard. But their language is changing to emphasise prevention as opposed to putting up with a hazard. The Belgians offer a very useful way to do this, with levels of prevention (see <http://www.meta.fgov.be>).

**Level 1 prevention** is best. It gets rid of a hazard or avoids introducing a new one (when you use the precautionary principle). This is where substitution using non-toxic alternatives is most effective. Public health practitioners would call this primary prevention.

**Level 2 prevention** (a.k.a. engineering solutions or controls at the source) limits the hazard at its source (reducing its spread). The hazard is still there but ways to prevent harm include:

- ventilation enclosing the hazard, taking it all out of the workplace (without damaging the environment);
- enclosures to reduce noise levels;
- isolating the hazard or the people who may be exposed to it; and
- wet methods (with dusts).

**Level 3 prevention** only limits or reduces harm by putting something between the worker and the hazard source.

Changes or "controls" along the path between the hazard and workers, include:

- local ventilation that does not enclose the hazard;
- general ventilation;
- mechanical guards/devices; and
- some administrative controls (e.g. breaks).

At the worker (controls at the worker), Level 3 prevention includes personal protective equipment/clothing (PPE) and:

- some administrative activities (e.g. rotating workers, because it just spreads the hazard around and may even make it worse for some, especially if hazards to back are involved);
- work procedures, training and supervision, emergency plans;
- housekeeping, repair and maintenance programmes, and hygiene practices/facilities; and
- things to take care of yourself (especially when you're stressed).

These solutions are the least acceptable way to try to fix a problem, although there are times when they're needed.



October 11, 2012

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

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

Dear Ms. Von Burg:

On behalf of the Writing Instrument Manufacturers Association ("WIMA"), I am making the following comments on the Department of Toxic Substances Control's ("Department" or "DTSC") proposed Safer Consumer Product Alternatives Regulation ("regulation") of July 2012.

WIMA is the U.S. and Canadian trade association of the pen, pencil, marker and eraser industry. Our forty plus members sell writing instrument products throughout the United States. Approximately ten to fifteen percent of our members' sales are in California. Accordingly, the proposed regulation is of extraordinary importance to this industry.

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

that a more focused approach in the regulation would address the practical problems raised by the scope and complexity of the draft.

WIMA also expresses the following concerns about the regulation:

- We remain highly concerned that the proposed regulation falls well short of meeting the practical, meaningful and legally defensible objectives Director Raphael set out when she was appointed to oversee this Initiative. The Department has proposed requirements that go beyond being necessary, clear, consistent, or legally valid based on the enacting legislation (AB 1879, 2008; SB 509, 2008).
- One of the most concerning aspects of the proposed regulation as currently drafted is the latitude which the Department reserves for itself to implement the program, providing itself with discretion at every decision point without providing sufficient clarity for the regulated community to understand what it must do to comply with the regulation. The current proposal would establish an all-encompassing program that appears to exceed the more modest intent of a practical approach. Indeed, virtually all commercially available products and their packaging will be subject to the regulation.
- It is difficult to reconcile the complexity of the proposed regulation with the marginal improvement in health and environmental safety it is likely to advance. Full implementation of the regulation as drafted would necessitate a huge new government program with a substantial budget requirement.
- Because the regulatory program builds off of each of the prior regulatory steps it is critically important to assure that each step in the process is necessary, clear, consistent, practical, meaningful, and legally defensible. Serious error is compounded with each successive step when the steps preceding are themselves defective. In order to implement a workable, science-based program, we believe the Department must find a comprehensive solution, rather than simply addressing one or two industry concerns at the expense of the others. Unfortunately, it is this piecemeal approach to addressing concerns which creates tremendous uncertainty within the regulated community.
- The first step of the regulation implementing AB1879/SB509 must be to identify and prioritize chemicals of concern in consumer products. Consistent with the statute we are firm in our belief that the prioritization and evaluation process must be based on exposure and hazard, and it must avoid duplication and conflicting regulatory requirements.

DTSC's draft Safer Consumer Products (SCP) regulations propose to use a list-of-lists approach to selecting Chemicals of Concern (CoC). DTSC has chosen certain lists prepared by global authoritative bodies as their starting point. Upon removal of statutorily exempt chemicals and duplicates, they predict a list of some 1200+ chemicals will result. Unfortunately DTSC stops at this point and (without further distinction or prioritization of the respective hazard traits, or environmental or toxicological endpoints that caused the chemical to be listed in the first place) identifies all of those 1200+ chemicals as CoCs. *This approach is seriously flawed unless a subsequent prioritization is undertaken to identify a discrete subset of the highest priority chemicals in that group of 1200+ which should rightly be identified as Chemicals of Concern.* No other state, federal or international jurisdiction apart from California has sought to begin with 1200+ actionable chemicals.

WIMA supports a two step approach, i.e., "chemicals under consideration" and "chemicals of concern." In this regard, we concur with GCA's recommendation that DTSC begin by identifying their list of 1200+ chemicals as "Chemicals Under Consideration." DTSC should next craft a manageable process focusing on chemicals which exhibit the greatest hazards, such as substances known to cause cancer or developmental or reproductive harm (CMR) and substances known to be persistent, bioaccumulative and toxic (PBT) in the environment as designated by US EPA and others. *A discrete subgroup of these chemicals with expected exposures in California should be identified as Chemicals of Concern.*

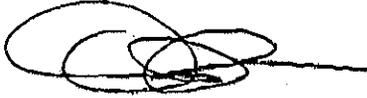
- The intent of the underlying statute, AB 1879 (Feuer, 2008), is to minimize the potential for exposure to hazardous chemicals of concern in consumer products and to encourage the innovation of safer consumer products; however, the proposed approach will create an unpredictable framework that will increase uncertainty in the business community.
- The proposal as currently drafted threatens vital intellectual property upon which innovation is based, requiring submission of information that is unnecessary and providing absolute discretion to the Department to make a decision about a trade secret claim.

Finally, it appears that the State of California fails to evidence any concern of the competing financial impact to all involved, including state, business and the public it seeks to protect. An extensive and fair assessment of implementation, maintenance and program operation costs at all of the multiple levels impacted should be completed. In a seriously eroding business climate, it is wrong for the

State to feel empowered to run up exorbitant costs to be borne by manufacturers, distributors and, in the end, the citizens of California. The cost of such a program will simply be passed on to them in the elevated price of the products they purchase and the employment opportunities that leave when it is not fiscally conducive for a business to operate in California.

We appreciate your consideration of our concerns.

Respectfully submitted



David H. Baker  
Executive Director

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

## GCREgs@DTSC

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**From:** David Bade <daveb@ampac-usa.com>  
**Sent:** Tuesday, October 09, 2012 3:04 PM  
**To:** GCREgs@DTSC  
**Subject:** California Green Chemistry Initiative - Proposed Regulations

Dear Regulations Coordinator Von Burg,

As a professional within the beauty industry, I wish to express my viewpoint on the proposed Green Chemistry Regulations. Our industry, including manufacturers, distributors, salon/spa owners and retailers, will be directly impacted by these regulations. As the regulations stand, there is too much uncertainty on the part of the DTSC on the economic impact on businesses both large and small, not only in California but throughout the United States.

The proposed regulations raise significant concerns for our industry, on issues such as trade secrets and confidential business information; excessive data submission requirements; product recall authority; retailer notification; a lack of scientific process to identify chemicals of concern; and many others.

I ask that you further postpone this initiative and publication of final regulations until the economic impact as well as other issues of concern can be assessed and any potential changes can be discussed at a future hearing.

Sincerely,

David Bade  


**From:** Joanna Abbott <joabbott903@comcast.net>  
**Sent:** Wednesday, August 22, 2012 4:37 PM  
**To:** GCREgs@DTSC  
**Subject:** Re: Support for a robust list of chemicals of concern as part of the Safer Consumer Products Regulations

Dear Director Raphael

As someone deeply concerned with the environmental and public health impacts of toxic chemicals used in commercial products, I wish to congratulate the Department of Toxic Substances Control (DTSC) on its proposed Safer Consumer Products regulations. They are a significant first step in changing how products sold in California are manufactured. These proposed regulations will help alleviate the threats to public health and the environment posed by toxics in consumer products.

At the heart of the proposed regulations is a robust list of Chemicals of Concern used in products that will be the focus of required alternatives analyses by product manufacturers. Since DTSC relied on internationally recognized lists of substances for which there is scientific evidence that they have the potential to cause harm, I fully support your Department's proposed list of approximately 1,200 Chemicals of Concern as a place to start. In future, as we learn more about the impacts of chemicals, including at low levels, it is likely that this list will have to expand. In the meantime, this proposed list will ensure that California addresses some of the most common environmental health threats, and provide manufacturers with guidance as to the chemicals they will need to find safer alternatives for in the years to come.

The Safer Consumer Products regulations represent an opportunity to protect public health and the environment while promoting innovation and economic growth in an international marketplace demanding safer products. This is an opportunity California cannot afford to pass up. I thank you and your staff for your hard work in developing this important program.

Sincerely,

Joanna Abbott

