

<b>30-DAY NOTICE</b>			
<b>LIST OF PUBLIC COMMENTERS</b>			
<b>#</b>	<b>NAME OF ENTITY</b>	<b>DATE REC'D</b>	<b>LATE</b>
40	Direct Selling Association	2/28/2013	
41	Dow Chemical Company	2/28/2013	<b>LATE</b>
42	DuPont	2/28/2013	
43	Electronics Industry	2/28/2013	
44	EMA (Truck & Engine Manufacturers Association)	2/28/2013	
45	European Commission	2/28/2013	
46	European Semiconductor Industry Association	2/28/2013	<b>LATE</b>
47	Farland Review_ESPR	3/4/2013	
48	Fashion Jewelry & Accessories Trade Association	2/28/2013	
49	Food Packaging Coalition	2/28/2013	<b>LATE</b>
50	Geiser, Ken	2/26/2013	
51	Gray Review_ESPR	3/4/2013	
52	Green Chemistry Alliance	2/28/2013	
53	Grocery Manufacturers Association	2/28/2013	
54	Hattis Review_ESPR	2/18/2013	
55	Hewlett-Packard Company	2/25/2013	
56	International Fragrance Association North America	2/28/2013	
57	Intertek Consumer Goods	2/28/2013	
58	IPC (Association Connecting Electronics Industries)	2/28/2013	
59	Japanese Industry Associates Committee	2/27/2013	
60	Japan Chemical Industry Association	2/25/2013	
61	Kirschner, Michael	2/27/2013	
62	Koch Industries	2/28/2013	
63	Los Angeles Area Chamber of Commerce	2/27/2013	
64	Los Angeles County Integrated Waste Management Task Force	2/28/2013	
65	Marin County Haz Waste Management JPA	2/28/2013	
66	Motor & Equipment Manufacturers Association	2/28/2013	
67	Natural Products Association	2/28/2013	
68	Orange County Business Council	2/26/2013	
69	Outdoor Power Equipment Institute	2/27/2013	
70	Personal Care Products Council	2/28/2013	
71	Plastic Pipe and Fittings Association	2/28/2013	
72	Plumbing Manufacturers International	2/28/2013	
73	Procter & Gamble Company	2/28/2013	
74	Professional Beauty Association	3/4/2013	<b>LATE</b>
75	Puk, Billy	2/28/2013	



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February 28, 2013

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

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

RE: DTSC's Informal Draft Regulations for Safer Consumer Products, R-2011-02

Dear Ms. Von Burg:

On behalf of the Direct Selling Association ("DSA") and its member companies, we appreciate this opportunity to comment on DTSC's Informal Draft Regulations for Safer Consumer Products, R-2011-02 ("Draft Regulations"). As written, the Draft Regulations could have a serious and negative impact on the 2.5 million Californians engaged in direct selling as a means to supplement their household income. These Californians sell approximately \$3.8 billion of products in California each year and contribute hundreds of millions of dollars in tax revenue to the State.

DSA is the national trade association representing 190 companies that sell products through personal presentation or home parties. Our companies sell and distribute their products through an independent contractor sales force, predominantly made up of individuals working part-time to supplement their family income. For purposes of DSA's comments, these individuals will be referred to as distributors. Under the proposed rules, these distributors would likely fall within the definition of "retailer" and therefore be subject to overly burdensome disclosure requirements.

As written, the definition of "responsible entity" under the Draft Regulations refers to the manufacturer, importer, assembler and retailer. Under particular provisions of the Draft Regulations, retailers are required to comply in situations where the manufacturer and importer fail to do so. For example, the retailer is required to comply with the consumer product disclosure requirements of § 69506.3. This Draft Regulation requires the responsible party to notify the consumer of any Chemicals of Concern that are in the product and/or any replacement

Candidate Chemicals as well as other information. Should the manufacturer and importer fail to do so, the burden is placed on the retailer selling the product.

We believe it is unsuitable to place the burden of reporting specific chemicals contained in products on an individual distributor. The Draft Regulation covers over 1,200 explicit chemicals with the potential to trigger a duty to disclose. The individual distributor has no control over the chemical composition of the products he or she sells. Nor does the distributor exercise any control as to how products are packaged and labeled by the manufacturer. The manufacturer of the product is the only responsible party that can meet the expectations of the DTSC. The onus should rest solely on the manufacturer, rather than the retailer to comply with DTSC's Draft Regulations.

Of additional concern to the direct selling industry is the disclosure requirement imposed under § 69505.7(d)(3) in situations where a responsible entity must perform an Alternatives Analysis ("AA") on a product. This section requires the AA Report to include the "name of, and contact information for, all persons in California other than the final purchaser or lessee to whom the manufacturer or importer directly sold the Priority Product within the prior twelve (12) months."

For purposes of the direct selling industry, this would require direct selling companies manufacturing products to report the name, home address, electronic address and phone number of each individual distributor to whom the companies sold their products. DSA has serious concerns related to the privacy issues associated with disclosing this information in an AA Report that could then be posted on the DTSC website for public comment pursuant to § 69505.1(d)(2).

Regulatory hurdles such as those described above will only discourage individuals from taking advantage of direct selling opportunities in California, and hence, reduce revenue in the State. Accordingly, on behalf of the direct selling companies doing business in California and the 2.5 million individual distributors residing in the State, the Direct Selling Association respectfully requests the DTSC amend the Draft Regulations to include an exemption for direct sellers.

On behalf of DSA's member companies and their individual distributors, thank you for your consideration of our comments. If you have specific questions regarding them, please contact me at 202-416-6408.

Sincerely,

A handwritten signature in blue ink that reads "Valerie Hayes". The signature is written in a cursive style with a small "x" at the end of the name.

Valerie Hayes, CAE  
Senior Director, Global Regulatory Affairs  
Direct Selling Association



The Dow Chemical Company  
Midland, MI 48674  
U.S.A.

2040 Dow Center  
February 28, 2013

California Department of Toxic Substances Control  
Office of Legislation and Regulatory Policy  
Ms. Krysia Von Burg  
Regulations Coordinator, Regulation Section  
P.O. Box 806  
Sacramento, CA 95812-0806  
Via E-mail: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Re: Proposed Safer Consumer Products Regulations (January 2013)**

Dear Ms. Von Burg:

The Dow Chemical Company (Dow) appreciates the opportunity to provide comments on the final draft regulations for Safer Consumer Products (SCP) regulations released on January 2013 by the California Department of Toxic Substances Control (DTSC or Department). DTSC's willingness to submit nine iterations of the SCP regulations not only reflects the commitment to continuous stakeholder engagement, but also the ultimate commitment to significantly reduce adverse impacts to human health and the environment. While Dow maintains its commitment to the initial goal of the California Green Chemistry Initiative, we remain concerned that the regulations as written will do little to encourage the innovation of safer consumer products, nor will the regulations foster a meaningful, practical regulatory environment.

As a world leader in using science and technology to shape chemicals management improvements, Dow is well positioned to use green chemistry to address the needs and challenges of a more demanding world. With over 700 employees and contractors at four manufacturing facilities in California, Dow has a vested interest in these regulations and has been actively engaged in the statutory and regulatory process since its inception. Dow is a diversified company with an industry-leading portfolio of specialty chemicals, advanced materials, agricultural sciences and plastics businesses. Dow delivers a broad range of technology-based products and solutions to customers in approximately 160 countries and in high-growth sectors such as electronics, water, energy, coatings and agriculture. Dow both manufactures and imports chemicals, products and raw materials that are potentially in the scope of this proposed regulation.

Dow recognizes and appreciates the recent revisions to make the regulations more workable for industry; however, we urge DTSC to give thoughtful consideration to the areas where the

Department could further clarify and simplify the requirements to make them more implementable. As noted in the attached addendum comments (October 2012), Dow's concerns remain focused on a fundamental premise: the SCP regulations lack clear, objective standards upon which predictability and compliance can be derived.

Dow applauds DTSC's attempt to address some of the concerns outlined by industry stakeholders in the January 2013 SCP regulations. Specifically, Dow supports the reference to the initial list of chemicals for consideration as the "Candidate Chemicals List" rather than "Chemicals of Concern." Focusing only those chemicals identified in the product-chemical combinations as "Chemicals of Concern" will hopefully mitigate the stigma and unwarranted market impact of product deselection.

While Dow also appreciates revisions that explicitly note that these regulations do not authorize DTSC to supersede requirements of other state or federal regulatory programs, adding to an already robust list of Candidate Chemicals will make it difficult to truly identify high-priority chemicals. When every chemical is a priority, none will be a priority.

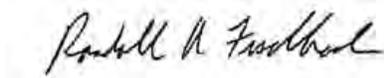
The latest revision outlines a better mechanism for tailoring "Chemicals of Concern" to priority product combinations. Yet, the evaluation of these priority products remains subject to broad DTSC discretion, which might dramatically impact how the regulations are actually implemented. Moreover, with regard to the evidence to substantiate DTSC's discretionary decision-making, there are still few boundaries on the types of information and analysis that DTSC can require an entity to produce. And, there are little or no criteria for judging the sufficiency of that information and analysis.

Establishing the sufficiency under a "weight of evidence" approach is critical when evaluating the toxicity of chemical substances and the other scientific questions pertaining to human health and the environment. In addition to adequate information, Dow supports having clearly-defined criteria for evaluating hazard traits and exposure around environmental and health concerns, which is why we were disappointed with the "Practical Quantitation Limit" in lieu of a reasonable *de minimis* threshold of 0.1% (1000ppm). This is a threshold that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program.

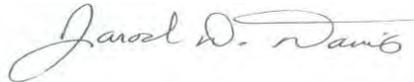
Precedent setting is not only recognized in areas of exposure assessments, but there is also precedent associated with laws protecting trade secrets. It is concerning to see that companies will still have to disclose chemical identities. The revision states that chemical identity may only be claimed as "trade secret" when the chemical is considered as an alternative and when a patent is pending for the chemical or its use. The protection of confidential business information (CBI) and trade secrets are considered sacrosanct among all business partners and industry representatives. DTSC continuously references its adherence to the existing legal framework for CBI and trade secrets laws and states that these regulations will not conflict with this existing framework. However, Dow believes that DTSC's goal of transparency may be undermined by the regulations because they compound the complexity of DTSC's trade secret determinations.

As noted in our October 2012 comments, we are interested in working with DTSC to further optimize the implementation of the regulations for Safer Consumer Products. It is imperative that DTSC be successful with this regulation so that it doesn't collapse under its own weight or add an undue burden on our ailing economy. We look forward to working with DTSC to ensure the effective implementation of this regulation.

Regards,



Randall A. Fischback  
Government Affairs &  
Public Policy Director



Jarod D. Davis  
Sustainable Chemistry Policy Director

**Addendum:**

Comments on SCP Regulations (October 2012)

## Comments on SCP Regulations (October 2012)

### I. Chemicals of Concern

Dow supports the design of regulations that truly focus on limiting exposure to, and adverse impacts posed by, Priority Products that contain Chemicals of Concern (COCs) in consumer products. This targeted approach encourages the evaluation of chemicals and products of concern where there is a reasonable or foreseeable pathway for exposure. The current Safer Consumer Products (SCP) regulations appropriately recognize that chemicals are to be evaluated based on their individual use in specific products and for identifying a further prioritization process for chemicals found in the initial priority products. However, these regulations do not specify objective criteria by which chemicals might be identified, nor does it state which of the ~1200 chemicals will be listed as COCs.

#### A. Identification of Chemicals of Concern

The objective of identifying and characterizing COCs is to focus on chemicals used in consumer products that meet specific hazard criteria and have exposure and use patterns that may pose risks. However, by identifying a broad list of COCs compiled by a variety of governmental, intergovernmental and academic interests, it is difficult to truly identify high-priority chemicals. When every chemical is a priority, none will be a priority. The substances on this very large list of COCs will likely remain listed indefinitely, even if they are used safely in consumer products, or even if they are not used in consumer products at all.

There does not appear to be a dedicated public comment period for this initial list of chemicals based on other authoritative bodies. The net effect is that over 1200 chemicals will be on the initial list of COCs without a proper chance for the public to comment on them. The draft thus stigmatizes chemicals and products containing those chemicals from the outset before the regulatory process of alternatives analysis and regulatory response have taken place. This will likely result in unwarranted market impacts because the market will move quicker to product deselection while DTSC struggles to keep pace with the COC identifications. Since the regulations do not include a clear or science-based process by which the DTSC will select which chemicals and products it regulates, the inclusion of such a broad list of COCs does not provide predictability and certainty to companies.

#### B. Tailored Approach to Chemicals of Concern

Dow supports regulations that are based on established scientific principles that define safe conditions for use and impose requirements to assure that use is controlled within predefined safe conditions. Such a system must rely on risk assessment and risk management principles that are predictable, flexible and capable of responsibly addressing society's economic, environmental and safety requirements.

Dow suggests that DTSC develop a risk-based chemical management system that screens chemicals to develop a narrower, focused list of COCs that actually represent the greatest potential risk. Such an approach will allow DTSC to conduct a step-wise, methodical evaluation of chemicals of concern in priority consumer products, provide appropriate notice and information to the public, enhance health and environmental protection, minimize the potential burden to both the State and the regulated community, leverage the considerable work already done by other governments (which is required by statute), and avoid unwarranted negative impacts on the market.

Dow is concerned that an initial list of some ~1200 COCs will unduly alarm the public without simultaneously providing the public with the confidence needed to ensure timely resolution or disposition of the products that contain those chemicals. DTSC may well be identifying hundreds of chemicals that have little or no use in consumer products, or which pose no risk of harm in those uses.

## **II. Priority Products**

Considering the magnitude of the proposed COC list, Dow believes it is appropriate for DTSC to only designate 2-5 priority products for the first 3-5 years of this program. This approach provides an opportunity for both industry and DTSC to better understand the regulatory challenges of the proposed framework. While Dow supports this approach, this portion of the regulations presents significant concerns for industry.

Dow appreciates that the Priority Products list is apparently intended to be risk-based, as it requires some consideration of exposure and the potential for harm. However, the current regulation identifies a vague process by which DTSC will prioritize and establish a list of Priority Products. It is unclear, however, how DTSC will objectively utilize the “Key Criteria” to assess and prioritize products based on a list of ~1200 potential chemicals of concern. An objective, step-by-step process should be constructed, based on credible, scientifically valid criteria that clearly outline the process by which DTSC will identify priority products. The use of a highly subjective process based on a narrative standard is not acceptable from a scientific or public policy standpoint.

### **A. Key Prioritization Factors**

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

## B. Aggregate & Cumulative Risks

The success of the product prioritization process hinges on the evaluation of aggregate and cumulative risks. As it is currently written, it is unclear when, how often and through what process DTSC will conduct an evaluation of a chemical's aggregate and cumulative effects. It is also unclear whether this refers to a human health or an environmental assessment of aggregate and cumulative risks, or perhaps both. Dow is not convinced that such an analysis is necessary for all chemicals of concern, all priority products or all potential alternatives.

Assessing aggregate effects and risks from the total exposure to a specific chemical from all different sources and routes requires considerable data and information that manufacturers of individual products do not have and cannot readily obtain. Manufacturers and/or sellers of a given consumer product would need information on each individual consumer's occupational exposures, medication and diet, information that would surely raise privacy concerns. In addition, individual companies cannot possibly know all of the possible sources and uses of any given chemical outside of their own control, thus rendering cumulative risk analysis impossible.

The lack of a process not only presents a challenge of predictability for industry, but it also poses significant challenges for actual implementation. Cumulative risk assessment is far from settled science. Scientific bodies do not yet agree on an accepted cumulative risk assessment methodology. In the context of the consumer product regulation, cumulative assessments would quickly become an onerous exercise with little practical meaning.

## C. Weight of Evidence

The SCP regulations do not currently include any "weight of the evidence" approach for evaluating the toxicity of chemical substances and other scientific questions pertaining to human health and the environment. It is a general principle of hazard assessment that all available data must be considered and the totality of relevant and reliable information integrated in order to arrive at a scientifically-defensible decision regarding chemical hazard. These regulations do not currently have a process to evaluate credible hazard trait data in a manner that addresses the relevance, quality and significance of the data. Dow supports the integration of exposure-based traits that will allow for the prioritization of chemicals based on widely-perceived objective, scientifically-based studies that have been vetted in an open, deliberative and transparent scientific process.

## D. Alternatives Analysis Exemptions

Having clearly-defined criteria for evaluating hazard traits and exposure around environmental and health concerns is integral to the success of chemicals management regulations. It appears that the approach to Alternatives Analysis Exemptions currently defined in the regulations will be arbitrary and inconsistent. Dow supports a reasonable de minimis threshold, or alternatives analysis threshold of 0.1% (1,000 ppm). This is a

threshold that has considerable precedent in the Globally Harmonized System for Classification and Labeling (GHS) and the European Union's REACH program. More importantly, it is a practical threshold that will avoid unnecessary assessments and reformulations based on the mere presence of trace amounts of a chemical of concern. DTSC should limit application of the regulation to intentionally added constituent chemicals.

While Dow appreciates DTSC's attempt to establish a unique approach to threshold limits, or lack thereof, the inconsistency with other federal and international bodies will create an unnecessary level of confusion for implementation. What criteria will DTSC use to trigger the need to establish a different de minimis level? Also, what standards will be used to evaluate the "available information" to warrant a higher or lower level? Dow recommends that DTSC carefully consider clarifying the process for establishing Alternatives Analysis Exemptions.

#### E. Minimum Detectable Concentration

The initial intent of the SCP regulations focused on minimizing potential exposure to COCs while spurring the innovation needed to select safer consumer products. Unfortunately, the current regulations are focused less on safe use and more on product deselection. Draft language indicates that DTSC will defer to the "minimum detectable concentration" level for the COC in the product. Dow is concerned that reliance on the limit of detection, in conjunction with precautionary language such as may "contribute to" adverse public health and environmental effects, and, deference to regulatory responses that provide the greatest level of "inherent protection," is establishing a framework focused on chemical elimination rather than safe use.

### **III. Alternatives Analysis**

The second stage of the alternatives assessment focuses on the comparison of alternatives. However, the criteria for determining a "demonstrable contribution" or a "demonstrable difference" are unclear. DTSC should define the process that will be used to evaluate factors relevant to the comparison of Priority Products and the alternatives. Dow would support the use of quantitative analysis tools like QSAR models to facilitate the comparison. These types of quantitative tools will help identify situations where there are other categories for which the alternatives are no better and possibly worse for potential toxicity or environmental hazards. Conducting comparative analysis under this rubric allows DTSC to conduct a more comprehensive review instead of merely relying on available qualitative information. Reliance on existing available information in this context presents a challenge because two purportedly "reliable" sources may not yield the same results or enjoy the same level of scientific standing. Dow recommends the use of quantitative tools that will enhance comparative assessment around exposure potential for consumer products.

#### **IV. Duplication of Worker Exposure Standards**

The overarching intent of the Safer Consumer Products regulations is to focus on exposure risks associated with consumer products. Thus, focusing on workers exposure in a retail setting seems to be an appropriate consideration for these regulations. Dow strongly believes that the scope of these regulations should focus on conventional consumer products in retail settings. There are OSHA exposure standards already in place for worker safety in industrial settings, and it would be unnecessary and duplicative for DTSC to appropriate its very limited resources in this manner. As just one of many examples, it seems reasonable to assume that the statute did not intend to contemplate additional regulations for an industrial worker filling railcars for shipment. Furthermore, some raw materials and intermediates may be “consumer products” under the regulations, and DTSC will have no authority to regulate the use of these materials outside of California. This creates a disincentive for California-based businesses, jobs, and operations. A manufacturer will actually be motivated to move out of state and sell back into California to avoid this duplicative regulation of the workplace. Not contemplated in this regulation is this “leakage” of jobs out of the state.

#### **V. Confidential Business Information**

The protection of confidential business information (CBI) and trade secrets are considered sacrosanct among all business partners and industry representatives. DTSC continuously references its adherence to the existing legal framework for CBI and trade secrets laws and states that these regulations will not conflict with this existing framework. However, Dow believes that DTSC’s goal of transparency may be undermined by the regulations because they compound the complexity of DTSC’s trade secret determinations. Several of the requirements for substantiation of trade secret claims are unnecessary and unauthorized by the statute (AB 1879) or other relevant trade secret statutes. The current framework outlines excessive requirements that should be revised.



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**Government Affairs, U.S. Western Region**

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February 28, 2013

Via email (gcregs@dtsc.ca.gov) and U.S. Mail

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

**RE: January 29, 2013 Post Hearing Changes to Proposed California Safer Consumer Products Regulation**

Dear Ms. Von Burg:

E. I. du Pont de Nemours and Company (DuPont) submits these comments in response to the post hearing changes made to the proposed California Safer Consumer Products regulations by the California Department of Toxic Substance Control (DTSC) on January 29, 2013.

DuPont has been engaged with DTSC in the development of its Green Chemistry Initiative for over five years. In particular, we have shared an industry perspective for a practical Alternatives Assessment Framework, which has subsequently been posted on the DTSC website. Along with many industry colleagues, we have invested time and energy toward reviewing and offering comments on each version of the developing regulation in an attempt to improve its workability and incorporate sound scientific approaches into the final rule.

We appreciate that the January 2013 revised regulations reflect positive changes. For instance, the requirement for the Alternatives Analyses (AA) to be performed by certified assessors has been eliminated. Also, the provision allowing DTSC to require that a new AA be performed based on receipt of new information has been removed.

However, several critical areas remain where further revisions are necessary to create a practical and meaningful regulatory program. Many of these areas are highlighted in the comments offered by the American Chemistry Council (ACC) on this topic. DuPont supports the ACC comments.

DuPont submits the following additional comments:

- **Public review and comment of AAs (§ 69505.1(d)) will be unproductive.** While we appreciate the removal of a certification requirement for an assessor, the added public review and comment will be resource-intensive and unproductive. The public, even if they are an educated public, is not in a position to have access to the information needed to evaluate these case-specific analyses. Moreover, scheduling and responding

to comments from these meetings will only prolong the process without added benefit to the decision-making.

- **The economic impact requirements under § 69505.6(a)(2)(C) are undeveloped and some will lead to the public release of competitive information.** The first requirement is to monetize and compare public health and environmental costs associated with the baseline and each alternative. This requirement is without a detailed explanation, including clarification of how these costs will be monetized and where the data sources will be. Valuation techniques are varied and complicated, and are only as good as the underlying data. The second requirement, to estimate costs to governmental agencies and non-profit organizations that manage wastes, oversee cleanup and protect resources is equally difficult to understand and to envision how this can be done. Finally, the requirement to develop and share internal cost impacts, including manufacturing, equipment and resource consumption costs will reveal important competitive process information that has the potential to compromise business positions in commerce.
- **Innovation cannot be scheduled.** The rigid timelines presented are unrealistic, as is the expectation that all data on alternatives will be available in the first 6-18 months of an assessment. The regulators seem unaware that industry may need to synthesize a new chemical to meet multiple performance criteria, and that performance and hazard data may not be immediately available. We are often required by our customers to go through a rigorous qualification process that may take many months before we are permitted by them to make product changes. The process of designing and testing a new material is time-intensive and iterative. If a substitute is not already readily available, which is often the case, time is needed to research and develop a new replacement material. Some candidates will be viable at the bench scale, but will not perform well at a larger scale, requiring the formulator to “start over”. Once a handful of viable candidates are identified, additional time is needed to ensure their stability and to perform important pre-production toxicity testing. This is part of the challenge of innovation and it cannot be scheduled to meet a regulatory deadline.

Thank you for the opportunity to comment on this very important matter. DuPont looks forward to continued collaboration with DTSC and our fellow stakeholders to develop and implement a workable Safer Consumer Products Regulation.

Sincerely,



Caroline Silveira  
Government Affairs Manager, Western Region



## Electronics Industry Comments on Proposed Safer Consumer Products Regulations (R-2011-02, January 2013)

The Information Technology Industry Council (ITI), TechAmerica, the Consumer Electronics Association (CEA) and the Semiconductor Industry Association (SIA), (hereinafter referred to as the “Electronics Industry”) are pleased to provide these comments on behalf of the information technology, consumer electronics, and semiconductor industries on the Proposed Safer Consumer Products Regulations (Proposed Regulations). Our industries have been longstanding stakeholders in the California Green Chemistry process, and we continue to appreciate the opportunities that the California Department of Toxic Substances Control (DTSC) has given to provide input on the Proposed Regulations as they have progressed through the drafting process. We also appreciate the several positive changes that are incorporated in this latest draft. We are concerned, however, that these Proposed Regulations still contain many onerous requirements and would add new provisions that are, for all practical purposes, unworkable. The Electronics Industry hopes to continue its dialogue with the DTSC, and hopes that the final regulations, when published, will represent a workable way to ensure the protection of human health and the environment.

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 first offer several overarching comments.

While the Proposed Regulations contain several significant improvements from the initial draft proposed regulations, we feel that several improvements that needed to be made, specifically in the regulatory response sections, still need to be addressed. Additionally, the DTSC has added significant new text, some of which is very problematic. We appreciate that the DTSC has removed the sections related to Certified Assessors. We also support the change that replaces the previous draft’s single “Chemicals of Concern” list with two independent lists: (a) a “Candidate Chemicals” List and (2) a separate Chemicals of Concern (“CoC”) list that is derived from the Candidate Chemicals List. We also appreciate the

removal of the overly broad “other regulatory responses” section, and for the addition of the definition of “Assembler.”

We will discuss these topics in detail in the specific comments below; however, we believe that the new definition of Alternative Analysis Threshold (AAT), and its tie-in to the Practical Quantification Limit (PQL) are unworkable. Further, we feel that the change in how trade-secret protection for chemical identity, where it is only available to companies that apply for a patent, is a significant shift in how confidential business information (CBI) has been traditionally handled in the US and California.

The Electronics Industry, as we have mentioned in our previous comments, continues to be concerned that the Proposed Regulations do not provide the regulatory certainty that cutting-edge industries require in order to research, plan, develop, manufacture and market new and innovative devices. For example, many common electronic devices found in consumer electronic stores take approximately 36 months between when they are conceptualized and when they arrive on the shelves. For more specialized technology, such as medical and industrial devices, this time-to-market is significantly longer. Knowing that a product being developed now can still be legally sold, under the same regulatory conditions, when it is placed on the market is critical to the ongoing research and development of these cutting-edge products. As we have mentioned in our comments on previous draft regulations, it is critical that any person, from regulators, corporate legal departments, and interested academics and NGOs, doing a regulatory analysis or determination under these regulations will be able to reach similar conclusions. Currently, the Proposed Regulations are overly deferential to the DTSC and too discretionary in several areas. We recognize that the Proposed Regulations must have the flexibility to accommodate a large number of potential situations, but the regulations must also provide for clear processes for prioritization and definitive triggers for regulatory responses. The Proposed Regulations must also ensure that the regulatory provisions will be revisited if there are significant changes to underlying science or market pressures.

We are concerned that as written, the Proposed Regulations may create a situation where different responsible entities may have different regulatory responses. The regulations must ensure that regulatory responses are not applied on a case-by-case basis but rather they must be applied uniformly to all responsible entities that are captured by a chemical-product pairing.

The Proposed Regulations did not address any of the Electronics Industry’s concerns that were previously communicated related to trade secret and confidential business information (CBI) protections. As mentioned above, the new proposed requirement that a company must file for a patent in order to claim CBI for chemical identity is counter to how

confidential business information has traditionally been protected in the United States. We will discuss this in more detail in the specific comments below.

Overall, the Electronics Industry does not believe that the DTSC has achieved its stated goal of making these regulations practical, legally-defensible and meaningful. As we have stated in the past, and continue to specifically identify in sections below, the Proposed Regulations still present a very onerous and costly regulatory scheme, both for regulated entities and the Department, that is predicated on significant paperwork requirements; an expansive alternatives analysis requirement that is difficult to meet; a vague and difficult to enforce regulatory threshold; and a general overreliance on testing that, especially for manufactured products (e.g., articles), will be difficult and expensive, while providing few, if any, environmental benefits. The DTSC has repeatedly stated that these new regulations must reward innovation; however, the lack of a uniform regulatory response, the significant burden on responsible entities throughout the supply chain, and lack of trade secret protections are likely to inhibit the introduction of new and innovative products into the state.

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

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

##### **Section 69501. Purpose and Applicability**

The electronics industry continues to have concerns with the stated purposes of the Proposed Regulations. As currently drafted, the purpose is confusing, ambiguous and uses subjective language that may be read to presume certain outcomes. We offer the attached revised "Purpose" statement, which more clearly outlines that the regulations are designed to establish regulatory processes for three distinct actions: (1) identifying Priority Products that contain Chemicals of Concern above certain threshold levels, (2) establishing alternative assessment requirements for evaluating alternatives to Chemicals of Concern that are contained in Priority Products above certain threshold levels, and (3) requiring implementation of regulatory controls, if warranted, to reduce potential exposures. This proposal is more consistent with the goals of the Proposed Regulations and also avoids the inclusion of subjective language.

- (a) Safer Consumer Product Regulations. This chapter specifies the process for identifying and prioritizing Priority Products that contain ~~and their~~ Chemicals of Concern above certain threshold levels, establishing the process for identifying and analyzing alternatives to Chemicals of Concern for the purpose of determining whether regulatory responses are warranted to protect public health or the

environment, and the process for implementing such regulatory responses, if warranted. ~~how best to eliminate or reduce potential exposures to, or the level of potential adverse impacts posed by, the Chemical of Concern in Priority Products. This chapter also specifies the regulatory responses that will be imposed by operation of article 6 or that may be required by the Department following completion of an alternatives assessment.~~

Subsection (b) also sets forth unclear requirements. For example, it is not clear which consumer products would be excluded under Subsection (b)(3)(A). Currently, the proposed rule provides very little guidance as to the types of existing regulatory programs that would meet both of these requirements. Industry needs a better understanding of the criteria that DTSC will use to determine whether these requirements are met. For example, the terms “same potential adverse impacts,” and “equivalent” are unclear in this context. The electronics industry suggests that the DTSC use more concrete criteria that would better demonstrate when these terms would be met.

Also, it is unclear if regulated entities would make the determination whether a certain consumer product is excluded under this subsection unilaterally or whether the DTSC would need to establish a list of regulatory programs that it deems meet these requirements before the provision can be applied. Typically, regulatory exclusions provide clear and unambiguous language so that regulated entities can clearly determine when they are covered by legal requirements. The DTSC needs to provide better clarity as to how this provision would be applied so that potentially regulated entities have more certainty when determining whether a consumer product is excluded from the rule.

### **Section 69501.1 Definitions**

We continue to have concerns with the proposed definitions contains in Section 69501.1 of the proposed Safer Consumer Products Regulation. We address each of the proposed definitions of concern below.

#### **(8) “Adverse waste and end-of-life effects”**

The electronics industry questions how the Department will apply this definition. Does it intend to consider the entire life cycle when assessing adverse waste and end-of-life effects? The product life cycle may be interpreted to include a very broad chain of activities that could potentially include raw material extraction, transportation, manufacturing, distribution and sale, use, and product disposal. The term “life cycle” needs to be appropriately defined to address the key life cycle product stages that would be relevant for this determination. As currently written, the definition is overly broad and could encompass activities that are so far removed from the product to be of relevance.

Furthermore, it is unclear as to the specific “adverse waste and end-of-life effects” that will be covered, particularly by subsections (C), (D) and (E) which all appear to address the impact of waste and byproducts on wastewater and treatment facilities and the resulting releases from such facilities. We recommend that this definition be revised to more clearly delineate the waste and byproducts that are relevant and the types of impacts that would be addressed by the rule. Subsection (D), for example, appears to be a subset of (C) and, therefore, may not be necessary or may be combined into subsection (C).

**(12) “Alternative Analysis Threshold” or “AAT”** is defined as “the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant.”

**(52) “Practical Quantitation Limit” or “PQL”** is defined as “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.”

Setting the trigger for an alternative assessment for contaminants at the PQL level poses numerous problems. First, the DTSC must recognize that the PQL for any given chemical will vary based on the matrix in which the chemical is contained as well as the specific test being used. The matrix can impact the degree to which the chemical can be detected as well as the appropriateness of any given analytical method to detect the chemical. Furthermore, analytical testing methods and detection limits are likely to improve over time, resulting in a PQL for any given substance that will change. Therefore, establishing the alternative assessment threshold for contaminants at the PQL level will create testing uncertainty and compliance difficulties. Responsible entities must select appropriate analytical method in Section 69505.3(a)(5). Use of the PQL may result in regulated entities determining their own regulatory thresholds, resulting in regulatory thresholds that may vary across regulated entities.

The DTSC should ensure that the definition of alternative assessment threshold and the definition of PQL do not reference each other. These two definitions should be distinct and independent concepts. The AAT should be a regulatory threshold that is set for each chemical and product combination. The PQL should be defined as an independent and non-regulatory testing measure, which may change and evolve over time based upon changes in testing methodologies. The PQL is relevant in determining whether the AAT is met, but it should not be the AAT.

The current alternative assessment threshold would require regulated entities to assess any Chemical of Concern if it exceeds the PQL in the product. This may force entities to spend significant resources to conduct AAs on products that contain negligibly measureable

quantities of a substance for which there are no data that indicates that the substance poses any risk at that PQL level.

We urge the DTSC to establish chemical-specific AATs. AATs that are set a “Zero”, “Not Detect,” or PQL level are not practical and must be avoided. As we mention in our comments in Section 69503.5, previous drafts of the SCP Regulations had the Department set an AAT when a chemical-product pairing was released. While we prefer a set de minimis number, as is done in the EU RoHS and REACH Directives, the approach where DTSC sets an AAT during each chemical-product determination is far preferable to the method outlined in this draft.

**(24)(A) “Consumer Product”**

It is not clear why the Department makes the distinction in subsection (C) between the types of entities that may have previously owned or leased the products. Such a distinction may result in the premature scraping of products that continue to have useful life, which is not an environmentally beneficial outcome. Certain consumer products may end up in refurbished or reused product inventories regardless of their previous ownership. These products should not be subject to the proposed rule – regardless of the type of entity that previously owned or leased them. The key trigger for regulatory purposes should be whether the date of manufacture of the product is prior to the date the product is listed as a Priority Product.

**26(A) “Contaminant”**

It does not matter whether a Chemical of Concern is intentionally added in order for it to potentially lead to an adverse effect if it is present in sufficient amounts. Also, it is impossible to determine “intention” analytically in order to prove compliance. The Electronics Industry suggests that the DTSC remove the definition of “contaminant.”

Further, the Proposed Regulations define the terms “contaminant,” “intentionally added ingredient,” “processing agent,” and “recycled material” as subsets of the same definition – definition 26. It is unclear why the DTSC is bundling these definitions. The Electronics Industry encourages the DTSC to define each term separately since they are not necessarily related.

**(29) “Economically Feasible”**

This definition is overly simplistic. The manufacturer’s operating margin is not the sole determinant of whether an alternative assessment will demonstrate that an alternative chemical is economically feasible. Other factors should be considered as well, including the direct cost of the alternative chemical and other costs across the chemical life stage, including product price; operation, maintenance, and repair costs over the life of the product; cost of regulatory compliance, disposal and other potential costs.

**(35) “Functionally Acceptable”**

We urge the DTSC to ensure that this definition assures that the “alternative product” performs the functions of the original product at a level that is considered to be “equivalent” to the original product in terms of function, performance, reliability, life span and product safety. The current definition’s focus on “sufficient performance” does not provide assurance that consumers will be provided with alternative products that meet the consumer needs, wants, and expectations that may have been provided by the original product.

*Recommendation:*

We recommend that this definition be changed to read:

(a)(31) “Functionally acceptable” means that an alternative to a Priority Product meets both of the following requirements: (A) The product complies with all applicable legal requirements; and (B) The product meets the performance and functionality requirements of the Priority Product. ~~performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.~~

**(42) “Life Cycle”**

This is a very broad definition of “life cycle” that, if used to define the potential adverse impact of consumer products, may prove to be onerous, burdensome and confusing. For example, packaging may best be evaluated as a separate product stream and not be considered as part of a consumer product’s life cycle for purposes of defining adverse impacts. Also, the definition of “waste” (as mentioned above) includes life cycle impacts, which may be difficult to assess and consider if they are broadly defined. We urge the DTSC to better scope the life cycle impacts that may be evaluated as part of a consumer product’s potential adverse impacts.

**(57) “Reliable Information”**

Since the Proposed Regulations establish a process that is focused on reducing consumer exposures to CoChemicals of concern that are contained in priority consumer products, the regulation should ensure that the information that is used to establish this regulatory process is based on reliable information that is scientifically sound. Apart from subsection (D), the definition of “reliable information” makes no mention of the need for the information to have a sufficient basis in science and to be corroborated by scientific experts. It is critical for the Safer Consumer Products Rule to be founded on peer reviewed and credible scientific information so that true consumer exposures are addressed and scarce resources are focused in the most efficient and effective way possible. There also needs to be an opportunity for information to be challenged to ensure that the information is truly reliable and reflective of sound science. We have suggested language in previous comments for a method for the DTSC to do this.

**(58) “Reliable information demonstrating the occurrence, or potential occurrence, of exposures to a chemical”**

This definition fails to sufficiently consider how “potential exposures” or “potential contributions” are reasonably foreseeable or likely to occur. The definition presumes that presence is equivalent to exposure, which is not necessarily the case. The definition needs to draw a tighter nexus between the presence of a chemical and potential consumer exposures, and there needs to be a nexus between a finding of “reliability” and scientific substantiation. Currently, the definition is lacking this foundation in science. Subsection (C) lists “evidence” although it is unclear what type of evidence would qualify. The electronics industry recommends that Subsection (C) be listed as “qualified scientific evidence” that was published in a scientifically peer reviewed report or other literature.

**(65) “Technically Feasible”**

We urge DTSC to include a requirement that “the technical knowledge, equipment, materials, and other resources available in the marketplace” are “equivalent” to the technical knowledge, equipment, materials, and other resources available in the marketplace that are used to develop and implement an alternative product or replacement chemical. Sufficiency does not necessarily mean equivalency. There also must be some recognition that an alternative chemical, component or product is capable of being produced by more than one entity in order to avoid anti-competitive impacts.

**Section 69501.4. Chemical and Product Information**

Section (a)(2) gives the DTSC the authority to collect any information from any party on any chemical and any product. This seems to be an attempt to echo requirements contained in the European Union (EU) REACH Regulations but because of the much broader scope of the Proposed Regulations, this would establish a significantly broader mandate than that given to the European Chemicals Agency in the REACH Regulation. It is probable that the responsible parties (i.e., manufacturers and importers) will not have specific physicochemical and toxicological data on specific chemicals that may be considered as Candidate Chemicals, but the process for adding chemicals to the Candidate Chemical list is in Article 2, and a process for obtaining specific chemical information should be included there.

*Recommendation:*

We recommend removing subsection (a)(2).

### **Article 3. Process for Identifying and Prioritizing Product-Chemical Combinations**

#### **Section 69503.2. Product-Chemical Identification and Prioritization Factors**

Section 69503.2 lists two criteria that must be met for any product-chemical combination to be identified and listed as a Priority Product, based on the “potential” for exposure and impact. As stated in our comments in the definitions, the word “potential” is very unclear. Although it is defined as a “phenomenon that is reasonable foreseeable based on reliable information,” it is unclear as to when this uncertain threshold of causation would be met. What factors would the DTSC use when making these determinations? Currently, both of these criteria are extremely uncertain and open ended. We encourage DTSC to help narrow these Principles to refine the prioritization process. Perhaps DTSC could use the expertise of a science-based committee, such as the Blue Ribbon Science Committee, to help refine these criteria to address potential exposures that are more likely to occur based on normal and foreseeable impacts across the product life cycle. Also, we request that the DTSC continue to require that both criteria must be met for a product-chemical combination to be identified and listed as a Priority Product.

Section 69503.2 also establishes factors that the DTSC would use to prioritize product-chemical combinations. These factors include an “evaluation of the product-chemical combination to determine its associated potential adverse impacts, potential exposures, and potential waste and end-of-life effects” by considering the factors described in the above mentioned principles for which information is “reasonably available.” This prioritization process relies heavily on the definition of “potential adverse waste and end-of-life effects” which (as we mentioned in the definition section) is a very open-ended definition. Does the DTSC intend to consider the entire life cycle when assessing adverse waste and end-of-life effects? The product life cycle may be interpreted to include a very broad chain of activities that could potentially include raw material extraction, transportation, manufacturing, distribution and sale, use, and product disposal. The term “life cycle” needs to be appropriately defined to address the key life cycle product stages that would be relevant for this determination. As currently written, the definition is overly broad and could encompass activities that are so far removed from the product to be of relevance. Also, the current proposed regulations would allow “any reasonably available” information regarding potential exposures to support a priority determination. The electronics industry strongly urges the DTSC to ensure that any information that is being used to support a priority determination to be based on sound science and not simply be “reasonably available.”

Section 69503.2(b)(2) recognizes that there are other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or Candidate Chemical contained in the products may already be regulated. This section provides a mechanism for the DTSC to consider whether such regulatory

requirements address and provide adequate protections with respect to the same potential adverse impacts, potential exposure pathways, and adverse waste and end-of-life effects. This section states that “the Department may list such a product-chemical combination as a Priority Product only if it determines that the listing would meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing.”

It is unclear how this provision would operate with regard to Section 69501(b)(3)(A), which explicitly states that consumer products that are already sufficiently regulated are excluded from the proposed rule, whereas section 69503.2(b)(2) merely states that the DTSC may “consider” whether existing regulations are sufficient. Section 69503.2(b)(2) also provides that regardless of existing regulation that addresses the potential adverse impacts, potential exposure pathways, and adverse waste and end-of-life effects, the Department may still list such a product-chemical combination as a Priority Product if the listing would “meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing.” As written, these two provisions appear to be in direct conflict with one another. Section 69501(b)(3)(A) provides an automatic exclusion if its criteria are met whereas Section 69503.2(b)(2) would provide the DTSC with the discretion to keep such consumer product in scope if such listing would “meaningfully enhance” public health or environmental protection, a mechanism that is very subjective and open to interpretation. This dichotomy in how consumer products that are subject to existing regulatory controls must be addressed. The Electronics Industry urges the DTSC to set a clear and definitive process for removing products that are already subject to existing regulatory controls from the Proposed Regulations. This process should be clear, consistent, and not open to arbitrary and subjective determinations.

Finally, Section 69503.2(b)(3) allows the DTSC to consider where there is a “readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible” when deciding whether to list a product-chemical combination as a Priority Product. As stated in the definitions section above, many of these terms are not fully defined and may insufficiently capture the complexities inherent in chemical substitution. Furthermore, it is unclear how the DTSC will use this information. Which sources will be considered reliable for purposes of evaluating whether a safer alternative is “readily available.” Again, it will be essential for the DTSC to rely on information that is grounded in sound science and that is peer reviewed by scientific experts.

### **Section 69503.3, Adverse Impact and Exposure Factors**

Section 69503.3, entitled “Adverse Impact and Exposure Factors” outlines the factors that the DTSC would use to evaluate product-chemical combinations for possible listing as a Priority Product. Subsection (a)(1)(C) states that the DTSC could consider the Candidate Chemical’s cumulative effects with other chemicals with the same or similar hazard traits and/or environmental and toxicological endpoints. However, chemical exposures may not be cumulative in practice. As a result, this factor may significantly overstate a Candidate chemicals’ potential exposure.

Subsection (b) provides the DTSC with the authority to evaluate a Candidate Chemical’s potential for exposure by considering designated factors, including the market presence of the product as measured by sales volume and household and workplace presence of the product. These factors presume that market, household or workplace presence is automatically linked to chemical exposure and this presumption is false in a significant number of cases.

Subsection (b)(4)(F) recognizes that containment of the Candidate Chemical is a factor that reduces potential chemical exposures and we greatly appreciate the DTSC’s inclusion of inaccessibility as an important factor in considering a Candidate Chemical’s potential exposure risk. Similarly, subsection(b)(4)(G) lists engineering and administrative controls as other mechanisms to be considered when evaluating a Candidate Chemical’s potential for exposure risk. The electronics industry agrees that inaccessibility, engineering controls and other factors may help reduce potential exposures and reduce the priority of a product, however, it is critical that the DTSC recognize that the mere presence of a Candidate Chemical should not be grounds for Priority Product listing.

### **Section 69503.5. Priority Products List**

This section sets for the process for the DTSC to establish and update the Priority Product List. Section 69503.5 (c) addresses “Complex Durable Products” which are defined in subsection (c )(1)(2) to mean a product that is assembled from 100 or more manufactured components and the product has an average useful life of five years or more and the product is typically not consumed, destroyed, or discarded after a single use. The subsection provides that the DTSC may not list as Priority Products more than ten components contained in a Complex Durable Product in a three-year period.

The member companies represented by our trade associations likely manufacture or assemble “complex durable products” based on this definition but it is not clear how the DTSC will interpret this definition. For example, is a computer screen a discrete component or is it composed of its subsection components (e.g., glass, housing, lamp, etc). Also, the term “manufactured component” is not defined. It is unclear how that term would be

applied to electrical and electronic equipment, which typically consists of hundreds of parts and pieces. Further, the “100 component” threshold for determining whether a product is a complex durable product seems arbitrary and may be too high. Since some products may contain fewer discrete components but also be very complex and durable, we suggest that the DTSC provide more guidance and clarification as to how this definition will be interpreted.

Section 69503.5 (e), entitled, “Priority Product Notifications to the Department,” would require each responsible entity for a product-chemical combination listed on the Priority Product list to submit a Priority Product Notification to the DTSC within 60 days after the product-chemical combination is listed as a Priority Product or 60 days after the product-chemical combination is first placed in the stream of commerce in California. Section 69503.7 would require each responsible entity for a Priority Product to notify the DTSC that its product-chemical combination is a Priority Product within 60 days after a product-chemical combination is listed as a Priority Product or within 60 days after a Priority Product is first manufactured or first placed into the stream of commerce in California after the date of its Priority Product listing.

Both of these sections appear to mandate the same requirements. They both require all manufacturers, importers, retailers, and assemblers associated with listed Priority Products to file notifications with the DTSC if their product-chemical combination is listed as a Priority Product. First, it is unclear how these notifications differ. Second, these notifications would amount to a staggering amount of paperwork that regulated entities must file and the DTSC must process. It is unclear why both of these notifications are required and why this tremendous submission of paperwork and duplication of effort is needed to reduce chemical exposures in consumer products placed in the stream of commerce in California.

In previous versions of the proposed regulations, the Alternatives Analysis Threshold exemption process was included in Section 69503.5. The electronics industry requests the DTSC to reconsider whether this section is the proper location for a de minimis exemption for Candidate Chemicals that are present in consumer products at low quantities that are deemed to present low exposure risks. The electronics industry opposes the current proposal, which is to exempt only contaminants that are present at the PQL level, which would introduce testing and compliance uncertainty.

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

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

Section 69504 provides a petition process that would allow any person to petition the DTSC to add to or remove chemicals from the Candidate Chemicals list or to add or remove chemicals or lists that the DTSC would use to identify Candidate Chemicals or to add or remove a product from the Priority Product list. The Proposed Regulations would require a petition to include specific requirements including the basis for the petition and information supporting the petition. Subsection (b) also contains limitations on any petitions, including the limit that a person may not petition the DTSC to delist any chemical identified as a Candidate Chemical if that Chemical is listed on one or more lists. The limits also prohibit petitions that would request the removal of entire chemical lists until three years after the effective date of the regulations and product-chemical combinations until three years after the date the product-chemical combination was listed as a Priority Product. These limitations appear overly onerous, particularly if a petitioner believes that its product-chemical combination was erroneously listed as a Priority Product. The process should allow some mechanism for addressing errors or improper or unreliable information.

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

This section contains a list of factors that the DTSC will consider when determining whether a petition will be denied or granted. While we appreciate the language that has been added that clarifies that these factors can also be used to petition for removal of a chemical from the Candidate Chemicals list or for a chemical list to be removed entirely, we are concerned that the new criteria found in subsection (b)(4) and (5) are overly strict and subjective.

First, subsection (b)(4) sets an overly high bar for petitioners to meet. If the petitioner can meet the first three criteria of the DTSC's Substantive Review analysis – having submitted (1) comprehensive, (2) high-quality information suggesting that the chemical ought to be removed and this conclusion is (3) supported by findings elsewhere – then it would seem that a strong case has been made for removal. If this conclusion can be made obsolete due to a simple technicality contained in (4), that the chemical still resides on one of the source lists used originally by the Department, then the process will be imbalanced and will unfairly favor additions over subtractions. While we understand the DTSC's desire to not make it overly easy to remove a chemical from the Candidate Chemicals list, removal must at least be achievable if such removal is warranted. We request that the Department remove subsection (b)(4) and consider chemicals which are petitioned for removal independently from the chemicals' source lists.

Second, we are concerned over the subjective analysis set forth in subsection (b)(5), relating to petitions for removal of an entire chemicals list. Currently, the DTSC must base its review of such petitions on “whether the entity responsible for the underlying list still conducts its

scientific assessments of chemicals in a manner that is substantially equivalent to, or as rigorous as, the manner in which it conducted its scientific assessments at the time of the initial adoption of these regulations.” This begs a couple of questions: how will the Department determine if the level of rigor has changed? What if the list lacked scientific rigor to begin with? This factor seems to require an overly-subjective assessment be made by the Department, which could lead to the dismissal of otherwise meritorious petitions.

As a whole, we remain 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 DTSC 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**

This section sets forth the guidance materials that the Department will post on its website to guide the performance of Alternative Assessments. Section 69505 does not prescribe any parameters or requirements for such guidance. Rather, the section simply states that the Department “shall make available on its website guidance materials to assist persons in performing AAs with this article” and “examples of AAs that are available in the public domain at no cost.” This is insufficient guidance for a regulatory program.

Regulated entities need to have confidence that the guidance and example AAs that will be posted on the DTSC website will meet accepted AA methodologies and assessment standards. Only AAs that will facilitate compliance with the regulations should be posted on the DTSC website. There are a number of AAs in the public domain that would not be consistent with DTSC's Safer Consumer Products Regulations and these AAs should not be provided as a regulatory model. The DTSC should provide an opportunity for public review and comment of proposed guidance materials and example AAs that the Department proposes to post on its website. There needs to be an opportunity for interested parties to review such documents and submit comments regarding their sufficiency as guidance materials. Key factors to assess would be whether such documents are comprehensive, reliable, credible, and scientifically sound.

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

We appreciate the DTSC adding subsection (b)(3), clarifying that the requirements of this article may be fulfilled by the responsible entity or another entity on its behalf.

Subsection (d)(2) now requires responsible entities performing an AA to post the preliminary AA report for public comment. This new section poses several issues. First, it is not clear what the process will be for posting a preliminary AA for comment. Must the responsible entity post the AA report on its own website and the Department just provides notice, or will the Department post the preliminary AA on the DTSC website? Second, it is not clear why responsible entities are now held to similar, and sometimes stricter, standards than the California Administrative Procedures Act. The DTSC must provide notice, but it clearly states (for example, in section 69502.3(d)) that the DTSC *may* respond to some or all public comments received. It is a potentially significant burden on the responsible entity to receive public comments directly, as there may be a significant number of comments, and not all of these comments may be substantive. Further, it is not clear in section (d)(1), who will determine which public comments are “relevant” for the sake of the preliminary AA report. It is likely that there will be differences of opinion between the commenters, different responsible entities, and the DTSC as to the “relevance” of these comments.

*Recommendation:*

Modify subsection (d) to reflect that: 1) DTSC will post the preliminary AA and manage public comment and 2) the DTSC will relay relevant substantive comments to the responsible entity.

**Section 69505.2. Removal/Replacement Notifications in Lieu of Alternative Analysis**

As written, for the relatively simple procedure of ensuring that entities are not covered if they remove the product from the stream of commerce in California or reformulate their products, the Proposed Regulations require two separate and very data-intensive submissions. It is not clear what regulatory, environmental or other benefit either report serves.

Subsection (b) lists the content requirements for the removal and confirmation notifications. The Proposed Regulations take over a full page to simply list the topics that must be included in the removal notification report. Much of this information will be confidential business information, such as the sales outlets in parts (4) and (5). Further, the Proposed Regulations rely on analytical testing and quality control protocols to attempt to “prove” that a chemical will not be present in a product. Most laboratory testing, especially at levels the Department is looking at, is very expensive destructive testing. The DTSC should rely instead on a combination of testing, when available, or adequate quality control, or quality assurance protocols to ensure compliance with the regulations. Furthermore, subsection

(D) assumes that in most cases, a chemical will be replaced simply with another chemical on a one-to-one basis. While this does sometimes occur, for complex products such as electronics, replacing a single chemical may require a complete chemical reformulation or potentially a redesign of the product. Including all of the information in subsection (D) for a re-designed product is a prohibitively long and complex process. We believe that these removal notices are an unnecessary paperwork exercise, and should be removed. The DTSC should instead rely on audits (per Article 8) of companies' compliance assurance systems to demonstrate that CoCs have been removed. If the DTSC believes these reports are necessary, they should be vastly simplified and not rely solely on testing to attempt to prove that chemicals are not present. In either case, the DTSC should not be requiring a responsible entity to submit two separate reports just to confirm that they changed their product.

The Electronics Industry recommends that subsection (c) be removed. First, it is nearly impossible for a manufacturer to do (1)(A) for almost any product that is not a simple formulation, and second, the "information" required in (1)(B) is not defined. Finally, it is not likely, given the complex supply chain for electronics products, that any manufacturer will be able to accomplish all of the certification requirements within 90 days as proposed in subsection (d).

### **Section 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis**

Please see our discussion of AAT and PQL in the definitions section above. As we have mentioned in our previous comments, we believe that the AAT notification is unnecessary. With the EU RoHS Directive and REACH Regulation, as well as every other chemical regulatory program in existence, there is no notification required if a chemical is below certain established threshold limits.

These notifications should not be required because they impose a regulatory burden on entities that are already aligned with the Department's goal of phasing out a CoC because the CoC is not in their product(s). It would be preferable to address non-compliance through another mechanism, such as auditing, rather than through an additional notification."

However, should the Department continue to require a threshold notification, we have the following concerns with the requirements below.

Subsection (a)(2) asks that a single responsible entity identify all other responsible entities for a product. It is the DTSC's responsibility to find out who the responsible entities are, and while the DTSC is typically invited to discuss the market specifics of a product with a

manufacturer, requiring the manufacturer describe its entire marketplace, potential competitors and all, may put responsible entities in an untenable position.

As with our concerns with other parts of the Proposed Regulations, this section overly relies on testing to demonstrate compliance. While we agree that a manufacturer should have the burden of proof of showing that a chemical is not present in their product, we believe that this should be done via audits and compliance checks, not via notifications.

#### **Section 69505.4. Alternatives Analysis Process and Options**

As written, subsection (d) allows for responsible entities to comply with the AA process by simply submitting a previously-completed AA and calling it their own. It is not equitable that one company may go through the entire AA process, complete with the time and costs that the AA involves, while another may simply review it, put their logo on it, and claim completion. While we appreciate that it is important for the DTSC to post examples of what it will accept as a “complete AA” on its website, allowing other companies to simply grab an existing AA is not good practice. We feel that companies can and should be able to model their analysis off another company’s but to allow companies to utilize the same exact AA may not be appropriate. We recommend that the DTSC clarify that this section applies to AAs completed by the same company (for example, a television manufacturer can apply an AA to computer monitors that it produces as well as television monitors).

It is not clear what the purpose of subsection (f) is. A thorough analysis will consider options, and may not perform a complete assessment of certain options if initial screening determines they are not viable. Either this subsection is redundant, as all AAs will have this, or the requirements are not clear.

#### **Section 69505.5. Alternatives Analysis: First Stage**

Subsection (c) lists the steps necessary for the initial evaluation of options. However, the Electronics Industry submits that this is overly broad for an “initial” screening. We suggest narrowing the factors that are examined here, and allowing responsible entities to eliminate options that will, based on a quick assessment, not be viable replacements. Options that pass initial screening can undergo much more thorough analysis in the Second Stage.

We appreciate the addition of subsection (d), allowing responsible entities to eliminate options based on additional information not listed in (c).

*Recommendation:*

Simplify subsection (c), allowing responsible entities to consider adverse environmental and public health impacts only, with further analysis in Stage Two.

### **Section 69505.6. Alternatives Analysis: Second Stage**

The Electronics Industry is concerned that there is too much analysis required in the Proposed Regulations. If all factors in the First Stage are then required to undergo a full analysis in the Second Stage, there are over 1,000 factors and areas that must each be individually assessed. The Electronics Industry suggests that the DTSC look to existing models to determine how factors are identified as relevant and how they are dismissed if they are not relevant. Requiring full analysis of all impact areas will slow the process and create bloated analyses with little impact.

Subsection (A)(1)(C) requires a complete analysis of all economic impacts. Unfortunately, there are no known methods to do this at this time. We suggest allowing the comparison of economic impacts as relevant to make a material selection, for example, if a responsible entity determines that a Chemical of Concern or Candidate Chemical represents the best option for economic factors. Otherwise, if an inherently safer chemical is the chosen option, the economic analysis is not as relevant.

### **Section 69505.7. Alternatives Analysis Reports**

This section refers now to four different reports that responsible entities may be required to submit at different times in the SCP process. This is a clear example of the unreasonable burden being placed on manufacturers with little or no environmental benefit.

As we mentioned in Section 69505.1, the mechanics for how the public should provide comment on the responsible entity's work product is not clear. Since the public is typically not an expert on the development and manufacture of covered products, we maintain that soliciting public input on the Alternatives Analyses will be of limited benefit. However, should the DTSC wish to garner public input, the DTSC should manage this process and provide relevant, substantive public comments to the responsible entity. We recommend modifying subsection (e) to reflect this.

We appreciate that the DTSC has removed the reporting of manufacturing location, but much of the other supply chain information, such as (3) and (4), are likely to be confidential information. Additionally, most responsible entities will not have assembler information requested in (e)(2). We recommend that the DTSC request supply chain information as

necessary in the regulatory response section rather than include it as part of the Alternatives Analysis report.

## **Article 6. Regulatory Responses**

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

While we appreciate the new consideration given to other regulatory requirements found in subsection (c)(2)(A), we believe that this section as a whole takes a step backwards by eliminating cost-effectiveness as a selection factor when choosing whether or not to impose a regulatory response. The limited cost factors found in subsection (c)(2) look at whether the selected response is more or less expensive for the responsible entity than another regulatory response, the potential for dual regulation, and the ability of the responsible entity to comply with the response. While these are important inquiries, they do not take the place of a robust cost-effectiveness consideration for regulatory response options that may have far-reaching and significant impacts on the private marketplace.

Additionally, we recommend that the DTSC add language clarifying that any regulatory response imposed will apply to all responsible entities captured by the chemical-product pairing. This even-handed application of a regulatory response would be fairer and more consistent than one imposed on a case-by-case, assessment-by-assessment basis, which could lead to different regulatory response obligations for different responsible entities. This makes additional sense as well because responsible entities would still be able to request a specific exemption from a regulatory response via the process laid out in Section 69506.9.

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

Subsection (f)(4) allows the DTSC to determine whether a regulatory response will apply to Priority Products ordered by a retailer prior to the effective date of the listing and still for sale when the final regulatory response determination is noticed, and/or Priority Products manufactured after the effective date of the listing but before the final regulatory response determination is noticed. We believe that either decision by the DTSC would lead to onerous results as either could lead to a recall of retailer inventory, which would likely be an overly-drastic measure to impose. Use of a “date of manufacture” trigger would help address these concerns.

We also disagree with the concept of finality for regulatory responses laid out in subsection (h). Regulatory responses imposed by the Department should not be locked in for all time,

but rather responsible entities should be given the opportunity to petition for a change in regulatory response. The DTSC would need to review such petitions, but the benefit in allowing an entity to make its case for why a particular regulatory response no longer has merit outweighs the cost of any uncertainty with regard to regulatory treatment. Especially since response options may lose merit with time, changing circumstances, or new information, such a petition process would add considerable fairness to the process.

### **Section 69506.2. Supplemental Information and Regulatory Response Revisions.**

We remain concerned that this section continues to provide the DTSC with an overly-broad mandate to require information be produced from responsible entities. First, that the DTSC may require an entity to obtain or develop "any information" supplementary to the AA Report within any time frame, is on its face an expansive authority that interjects unnecessary uncertainty into the process. This section should thus be modified to further limit what information the DTSC can require be produced, as well as clarifying that a "reasonable" time frame be given for producing it to the DTSC. Information requests should be finite and an entity's response should be good for a reasonable period of time, so that the responsible entity is not continuously being forced to respond to additional information demands of the DTSC.

### **Section 69506.3. Product Information for Consumers.**

The changes made to this section only exacerbate existing concerns we have over the ineffective and burdensome means that can be mandated on responsible entities to disseminate information to consumers. The amount of information required by subsection (b) remains so substantial that it will invariably lead to consumer confusion, saturation, or dismissal. Additionally, a responsible entity will find it extremely difficult to fit all of this information onto the product packaging, which will likely be their only option as retailers will not voluntarily provide a placard at the point of sale. Thus, again manufacturers are faced with a potential regulatory response that will require a tremendous redesign of product packaging in a way that may dilute their brand and product appeal, all for a requirement that will provide dubious benefits to consumers.

We would strongly urge the DTSC to think creatively when it comes to providing this information to consumers, rather than remaining tied to the approach found in previous iterations of the SCP regulation. Research continues to show that beyond immediate hazards, labeling of a product is an ineffective way to warn consumers of potential hazards. At what point is more information too much information for a product package? What size font would be needed to fit the information in subsection (b) on a product, let alone on

smaller products? Would only English be acceptable, or would multiple languages be required? More concerning, what immediate, tangible harms (e.g. "Warning: Choking Hazard") will be dismissed by the consumer due to a lengthy and distracting paragraph provided directly on the packaging regarding a replacement Candidate Chemical's known hazard traits and environmental and toxicological endpoints?

To a degree, manufacturers are facing the lone option of attaching a booklet or manual to the exterior of the product packaging in order to comply with this regulatory response. What benefits are derived from such booklets and at what cost? The alleged benefit is that all of this information is in one place available to the consumer prior to the point of sale without opening the product packaging. The costs, however, include but are not limited to: (1) increased costs to the manufacturer to produce such booklets and attach them to their products, (2) loss of packaging design appeal, (3) environmental costs associated with the production and printing of this information in booklet form and attaching them to every product, (4) increased product weight, meaning greater shipping costs and fuel required, and (5) the putative benefit such booklets would ultimately serve, given the low likelihood that consumers will read them prior to sale.

Manufacturers need more flexibility to provide this information to consumers in more effective ways – particularly ways that, at the very least, recognize the digital age in which we live. Websites, QR codes, or other methods where information is made available to customers and retailers and that can be retrieved on demand provide a logical alternative to the increasing stacks of information that could be required to be included on product packages. It should be mentioned that our companies do not face labeling requirements in a vacuum of California Green Chemistry – rather there are numerous regulatory regimes domestically and internationally that require their own labeling as well and which our companies must comply with in order to continue doing business, creating jobs, and fueling economic activity. Eventually, the tipping point is reached and consumers lose out on the most important information that should be provided to them, manufacturers suffer the financial and design consequences of rigid labeling mandates, and regulators are left to pondering if there might have been a better way.

Additionally, from a practical perspective, the manufacturer likely does not have all the information required by subsection (b)(3), nor is it clear how they will make the determination that the product must be disposed as hazardous pursuant to subsection (b)(4). These are straightforward issues that, when combined with the higher-level concerns over rigid product labeling requirements, make for a regulatory response that injects substantial uncertainty into the revised proposal. We ask that this section be amended to provide much-needed flexibility to responsible entities to disseminate information to consumers in the ways that are most effective and not necessarily limited to labeling of the product package.

### **Section 69506.5. Product Sales Prohibition.**

A key concern we have with this section is the determination of whether or not an alternative is technically and economically feasible. It appears that the DTSC will make this determination but it is unclear how they will arrive at such a conclusion. This would seem to be a key point as it appears to separate those that may be subject to a product sales ban, and those that may not. However, subsection (b) further explains that even for products where no safer alternative exists, the Department can impose a sales ban. This outcome seems to steer the program away from its core function: to encourage the design or redesign of products and processes from manufacture, use and disposal in a way that minimizes exposure to hazardous substances. Banning a product that provides utility to society simply because it cannot be redesigned in a way envisioned by the regulation would seem to distort the purpose of Green Chemistry and use its process to achieve results not originally envisioned by those who supported it.

This section also assumes – as others sections do – that there is a test available for determining the presence of a material in a particular product. How are responsible entities and the Department going to ensure compliance of something that cannot be tested?

Additionally, the "exceptions" identified in subsection (c) are not really exceptions at all -- rather, they reference products that do not contain a Chemical of Concern or that the responsible entity has stopped selling the product. From an enforcement perspective, how will the DTSC know which products contain a Chemical of Concern and which do not? These are critical questions for companies' legal compliance audits and will create a further challenge for responsible entities seeking to meet their obligations under the regulation.

### **69506.6. Engineered Safety Measures or Administrative Controls.**

We recommend that for consistency and clarity purposes, that the Department remove the "integrally contain" language found in subsection (a) and replace it with language requiring the manufacturer to control "accessibility" to the Chemical of Concern or replacement Candidate Chemical. Accessibility is a preferred term here as there are defined tests for accessibility, and the term is already used in the prioritization process.

Additionally, there needs to be some type of threshold for presence of a Chemical of Concern, and its metabolites, degrade, or reaction products because many of these Chemicals of Concern are naturally occurring and may have multiple metabolites. Absent a

reasonable threshold, the responsible entity may find itself in the position of having to implement engineering or administrative controls over a substance it has no control over.

#### **69506.7. End-of-Life Management Requirements.**

We appreciate the addition of a manufacturer collaboration option in subsection (b) of this section. However, as many of our companies already offer their own successful product take-back programs to their customers, and given the vibrant post-consumer marketplace for electronics, we believe this section should specifically allow a responsible entity to show that it has an existing plan in place that is effectively taking back the product in question. This mechanism could be included in the "Alternative End-of-Life Programs" subsection (d), or in the "Exemption" subsection (e). This would help recognize the voluntary efforts that a responsible entity may already be making to manage its products after use, and avoids the undesirable result where an entity must completely abandon its current program and the infrastructure already in place for a separate program required via regulatory response which may offer only marginal gains in collection.

#### **69506.8. Advancement of Green Chemistry and Green Engineering.**

We appreciate the additional language at the beginning of this section that helps clarify when this regulatory response might be imposed on a responsible entity. That said, this regulatory response still creates a substantial amount of uncertainty for responsible entities in the process. 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. We ask that this Section 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.

#### **Section 69506.09. Exemption from Regulatory Response Requirements.**

The changes made to this section in the revised proposal do not diminish our concerns that this section appears duplicative of work that the DTSC 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 that effectively address chemical exposure, the product should automatically 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.

#### **69506.10. Regulatory Response Report and Notifications.**

We appreciate the changes made to this section that recognize that the responsible entity can only account for those persons to whom they directly sell the product when notifying its supply chain. However, we still believe the regulatory response notice to the DTSC required under subsection (c) is unnecessary, as DTSC should assume but confirm compliance as needed, such as by requesting compliance documentation.

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

#### **Section 69509. Assertion of a Claim of Trade Secret Protection.**

The Electronics Industry has serious concerns with subsection (g), which explains that a replacement chemical that is the subject of a hazard trait submission may be temporarily masked only if a patent application is pending for the chemical or its contemplated use in the product.

As a threshold matter, the requirement that one can only claim as trade secret a replacement chemical that is the subject of a patent application improperly conflates two distinct forms of intellectual property protection, and does so in a manner which seriously erodes existing statutory and common law property rights currently guaranteed to owners of trade secrets. Under both the model federal statutory law – the Uniform Trade Secrets Act – and both state common law and statutory law, an entity may claim as a trade secret any non-publicly-disclosed information from which the entity derives or may derive an economic advantage, for as long as reasonable measures are taken by the entity to maintain the information as a secret.

Under current law, the property right in a trade secret is maintained as long as the information is kept secret, i.e. not publicly disclosed without an express written obligation of confidentiality. There is no requirement under any current statutory or common law that the holder of a trade secret must seek patent protection in order to be able to maintain its property interest in the trade secret, nor is there any requirement that one must disclose trade secrets, absent a written obligation of confidentiality binding the receiver of the trade secret information.

It is a bedrock principle of intellectual property law that an entity making a discovery or invention may freely choose whether to seek the potentially unlimited temporal protection of a trade secret, or in the alternative, file a patent application and thereby waive trade secret protection. The benefit of the latter course is that upon publication of the patent application, the entity has the possibility of obtaining a 20-year limited exclusive right upon the issuance of a patent covering the invention.

Many companies rely on a combination of trade secret and patent protection in order to protect their discoveries and inventions. In some cases, where the trade secret is not readily discernible from the product, electing trade secret protection is the preferred intellectual property protection scheme and a patent will never be filed. In fact, some entities may elect never to file a patent application, relying instead on trade secret protection to protect their discovery or invention (e.g. Colonel Sander's "secret" chicken recipe, or Coca-Cola Company's "secret" formula for COKE).

The revised proposal thus errs in making three critical assumptions.

First, the proposal errs in assuming that entities will elect to file a patent on every discovery that provides them with a competitive advantage. As noted above, in many cases, particularly where the discovery or invention is a product formulation that cannot readily be analyzed or which is not discernible by inspection, an entity will choose trade secret protection over prospective patent protection. Again, this is due to the potentially unlimited time frame for maintaining the economic advantage obtained from the trade secret, as opposed to the limited 20-year exclusive right derived from filing a patent -- assuming the patent ever issues.

Second, the proposal errs in assuming that any trade secrets in that invention or discovery will or should lapse when the patent is granted or denied. Those trade secrets would actually lapse once the patent application is published (i.e. publicly disclosed without a written obligation of confidentiality) approximately 18 months after the original filing date. This publication date is typically 2-3 years before the patent would ever be granted, and likely at least 5-7 years before the patent application would ever be "finally" denied, after exhaustion of all rights of appeal of that denial, including appeal to the U.S. Supreme Court.

Third, the proposal errs in assuming that it has a legally defensible basis to require entities to either waive their property rights with respect to their existing trade secrets, or to force those entities to take on the considerable expense of preparing, filing, prosecuting and maintaining patent protection over all of their inventions and discoveries in order to continue to avail itself of its statutory and common law rights, even if only for the limited 18-month time interval for the patent to publish. The waiver requirement would likely be successfully challenged in court as an unconstitutional "taking" of property; the "patent-

filing" requirement would likely be successfully challenged in court as an unconstitutional "forced expenditure" inconsistent with the Constitutional intent underlying the Patent Act, 35 U.S.C. Section 101 et seq. In other words, we believe it would be unconstitutional to apply the Patent Act in a manner which required inventors to seek patent protection for all of their discoveries, or alternatively, to require public disclosure of these discoveries, thereby causing loss of their existing property interest in maintaining the discovery or invention as a trade secret.

An additional concern is that requiring the disclosure of trade secret product formulations in a manner that does not impose an affirmative obligation on the receiving party not to disclose will automatically trigger the loss of trade secret protection, because such disclosure is viewed as a public disclosure. The only way that entities could disclose trade secret product formulation information without losing their economically valuable trade secret protection and the economic advantage derived from the trade secret, is if the disclosure is made under a written obligation of confidentiality and non-disclosure of the trade secret by the receiving party. Absent such a requirement, DTSC's proposed disclosure requirements would likely have the unintended consequence of placing American -- and more particularly California companies -- in the untenable position of having to disclose their most economically valuable trade secret product formulations in a manner which ultimately would place those trade secrets in the hands of foreign competitors.

For all of the foregoing reasons, we do not believe that the revised proposal properly addresses the substantial unintended economic effects of requiring mandatory disclosure of trade secrets. The electronics industry recommends that subsection (g)(1) be removed, and that the trade secret protections be revised to be consistent with existing California and Federal trade secret protections.

## **Conclusions**

ITI, TechAmerica, CEA and SIA wish to thank the DTSC for its ongoing work on the Proposed Safer Consumer Product Regulations, including its continue work to solicit public input on the draft regulations. However, the Electronics Industry strongly believes that the Proposed Regulations require continued and significant effort to meet the DTSC's stated goals of achieving a practical and workable regime. We hope that the DTSC is still open to suggestions for improvements and we hope that our comments are thoughtfully considered. The Electronics Industry is committed to working with the Department to identify policies and improvements that will achieve environmental protection, but still enhance innovation. 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), Robert Callahan at (916) 443-9088 or [robert.callahan@techamerica.org](mailto:robert.callahan@techamerica.org),

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Sincerely,



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#### *About ITI*

The Information Technology Industry Council (ITI) is the premier advocacy and policy organization for the world's leading innovation companies. ITI navigates the relationships between policymakers, companies, and non-governmental organizations, providing creative solutions that advance the development and use of technology around the world. Visit [itic.org](http://itic.org) to learn more.

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TechAmerica is the leading voice for the U.S. technology industry – the driving force behind productivity growth and job creation in the United States and the foundation of the global innovation economy. Representing premier technology companies of all sizes, we are the industry's only trade association dedicated to advocating for the ICT sector before decision makers at the state, federal and international levels of government. With offices in Washington, D.C., Silicon Valley, Brussels and Beijing, as well as regional offices around the U.S., we deliver our members top-tier business intelligence and networking opportunities on a global scale. We are committed to expanding market opportunities and driving the competitiveness of the U.S. technology industry around the world. Learn more about TechAmerica at [www.techamerica.org](http://www.techamerica.org).

#### *About CEA*

The Consumer Electronics Association® (“CEA”) represents more than 2,000 companies involved in the design, development, manufacturing, distribution and integration of audio, video, in-vehicle electronics, wireless and landline communications, information technology, home networking, multimedia and accessory products, as well as related services that are sold through consumer channels.

#### *About SIA*

The Semiconductor Industry Association (SIA) is the voice of the U.S. semiconductor industry, one of America's top export industries and a bellwether measurement of the U.S. economy. Semiconductor innovations form the foundation for America's \$1.1 trillion dollar technology industry affecting a U.S. workforce of nearly 6 million. Founded in 1977 by five microelectronics pioneers, SIA unites over 60 companies that account for 80 percent of the semiconductor production of this country. Through this coalition SIA seeks to strengthen U.S. leadership of semiconductor design and manufacturing by working with Congress, the Administration and other key groups. The SIA works to encourage policies and regulations that fuel innovation, propel business and drive international competition in order to maintain a thriving semiconductor industry in the United States. Learn more at [www.sia-online.org](http://www.sia-online.org).

February 28, 2013

**Via e-mail (draphael@dtsc.ca.gov)  
and 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 Revised Draft Safer Consumer Product Regulations**

Dear Ms. Raphael:

Through this correspondence, the Truck and Engine Manufacturers Association ("EMA") is submitting its comments regarding the revised draft Safer Consumer Products Regulations ("Revised Regulations") that the Department of Toxic Substances Control ("DTSC") released for public review and comment on January 29, 2013. EMA submitted its initial comments on October 10, 2012, in connection with the DTSC's July 2012 version of the Regulations, which comments are incorporated by reference herein. EMA appreciates the opportunity to submit these supplemental comments, and we look forward to working with DTSC staff to ensure that the DTSC adopts final Regulations that are lawful, feasible and cost-effective. As was the case previously with respect to the DTSC's July draft, the proposed Revised Regulations do not satisfy those requisite criteria for a valid rulemaking.

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, "complex durable products" - - under the Revised Regulations' sweeping definitions, and so could fall under the multi-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 Revised Regulations at issue.

EMA continues to support 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, efficient 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 efficient 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 and highly durable goods that are manufactured and assembled by EMA's members. To the contrary, and as detailed below, the Revised Regulations remain fundamentally unworkable and infeasible in that context.

As before, EMA endorses and incorporates by reference the comments that the Complex Durable Goods Coalition ("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, notwithstanding the DTSC's proposed amendments, the Revised Regulations are still likely to create unlawful duplication and conflict with existing comprehensive regulatory programs. Accordingly, DTSC must still address this threshold issue through appropriate and *unambiguous* exemptions and "off-ramps" before finalizing the Revised Regulations. EMA's comments also will discuss the inherently unworkable nature of the Revised Regulations, which, in the context of the complex durable products manufactured, assembled and *imported* 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 is the clear conclusion that the Revised Regulations remain fundamentally ill-suited to the types of products manufactured and assembled by EMA's members - - products that are comprised of literally 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 originally submitted to the DTSC on October 11, 2012, and that the Global Automakers originally submitted to the DTSC on October 8, 2012, the definition of "consumer products" should be revised to exclude the engines and emissions-related equipment (including all related service parts) manufactured and assembled by EMA's members, due to the inherent conflicts with existing regulatory programs as detailed below.

### **The Revised Regulations Still Unlawfully Conflict With Existing Regulatory Programs**

As an initial matter, and despite the language added to draft regulatory section 69501(a)(3), the Revised Regulations still are likely to create unlawful conflicts with other existing regulatory programs. More specifically, with respect to the emissions of air pollutants, including greenhouse gases, ozone-forming compounds and particulate matter, engines, vehicles and equipment already are subject to comprehensive and technology-forcing emission standards

and other emission-control requirements as 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 of air pollutants 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 and broad 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 any other air pollutants - - from any mobile sources.

In recognition of the force and scope of federal preemption, the Revised 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 expressly excluded *in unambiguous terms* 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 prohibited 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. (See Revised Regulations, sections 69503.2(b)(2) and 69506.9(b)(6).) Nor is it subject to the DTSC’s determination and discretion, as the Revised Regulations would have it, to assess whether the DTSC’s potential requirements might provide “protection that is equivalent to or greater than”

the protection afforded by CARB's and EPA's regulatory programs. (See Revised Regulations section 69501(a)(3).) To the contrary, the Clean Air Act as well as the Health and Safety Code take those matters out of DTCS's hands. Again, in this regard, the DTSC is absolutely preempted. Accordingly, the Revised Regulations must be revised to state *unequivocally* that the DTSC expressly excludes, without qualification, from the definition of consumer products any products that are subject to the protections of federal preemption under the Clean Air Act or other federal statutes and regulations. Without such a clear-cut exemption, the Revised Regulations will serve only to foster and engender uncertainty and potential litigation as opposed to consumer safety.

The Revised Regulations also remain 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. As EMA noted in its earlier comments, those Federal Motor Vehicle Safety Standards regulate the design and performance of almost all the major components and assemblies 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 various vehicle "components" (including, under the DTSC's broad definition, various "assemblies" or "subassemblies") as priority products, it would almost certainly create ripple effects that would spill over into, and thereby conflict with, 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 complex durable goods - - specifically engines and emissions-related components - - will almost certainly interfere and 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 federal laws and the underlying California statute expressly prohibit. See Health and Safety Code § 25257.1. The net result is that DTSC should not endeavor to regulate those components of complex durable goods that are already subject to

comprehensive health and safety regulations. Rather, those already-regulated components should be expressly exempt under the DTSC's final regulations.

**The Revised Regulations Should Apply To Component Manufacturers,  
Not Assemblers Or Importers Of Complex Durable Products**

The conclusion that the DTSC's Regulations should not apply to currently regulated complex durable products is buttressed by the fact that the DTSC's regulatory scheme is fundamentally illogical when applied to the components of the complex durable goods manufactured and assembled by EMA's members. Imposing mandates for the redesign and remanufacture of components on entities that are not in the business of designing or manufacturing components is not only inherently illogical and unreasonable, but unworkable as well. The Revised Regulations attempt to address this issue by excluding product "assemblers" from the definition of product "manufacturers," but that revision is insufficient on its own to cure the Regulations' fundamental defects. More specifically, the same fundamental problems remain if the assemblers of complex goods may be deemed "importers."

By way of background, 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 and assemblies 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.

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, as EMA explained in detail in its initial comments, the DTSC's regulations were originally directed at the wrong entities in the supply chain. The regulations sought to impose mandates that ought 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 created an inherently impractical and unworkable situation.

The DTSC has sought to address this core defect by creating definitional distinctions between product “manufacturers,” on the one hand, and product “assemblers,” on the other. Through that distinction, the Revised Regulations will not treat product assemblers as the “responsible entity” for many of the Regulations’ requirements relating to alternatives analyses and regulatory responses. While that is certainly a step in the right direction, it does not address the full scope of the problem with respect to vehicle, engine and equipment manufacturers.

More specifically, some vehicles, engines and equipment are manufactured and assembled outside of the U.S. and then brought into U.S. for sale by the manufacturer/assembler. The manufacturer/assembler’s role does not change in that process; it still does not have control over the formulation and fabrication of the myriad component parts supplied by the upstream component manufacturers. Yet, under this scenario, the Revised Regulations would nonetheless cast the manufacturer, not as an assembler (the proper designation), but rather as an “importer.” Cast as an importer, the manufacturer/assembler could be seen as a “responsible entity,” thereby defeating the purpose of the Revised Regulation’s attempt to provide appropriate regulatory relief to assemblers.

To remedy this defect in the Revised Regulations, and just as the definition of “manufacture” was amended to exclude acts that meet the definition of “assemble,” the term “importer” should be amended to exclude any entity that meets the definition of an “assembler.”

In the end, when dealing with complex durable goods, it is not the component assemblers or the importers of assembled products that should be the regulated and responsible entities. Accordingly, the Revised Regulations need to more fully account for the inherent lack of control that product assemblers have over the chemical content of product components by exempting assemblers not only from the definition of “manufacturer,” but from the definition of “importer” as well.

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

Turning to the logistics by which DTSC proposes to implement its multi-step program, fundamental revisions are still required to those aspects of the Revised Regulations as well. Under the Revised Regulations, engines, vehicles and equipment would be included within the DTSC’s proposed definition of “complex 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 Revised Regulations section §69503.5(c).) Moreover, given the overly-broad manner in which DTSC has defined the term “component,” the DTSC could designate up to ten (10) separate product “assemblies” or “subassemblies.” In the case of vehicles, engines and equipment, the net result of designating up to ten (10) product “assemblies” could end up mandating a redesign of virtually the entire vehicle, engine or equipment. Thus, the potential scope of the DTSC’s program is wholly unreasonable as it relates to the complex durable products manufactured and assembled by EMA’s members. Accordingly, and at the very least,

the scope of the DTSC's proposal needs to be narrowed substantially to make the Regulations workable on even a theoretical basis. To that end, the terms "assembly" and "subassembly" should be deleted from the definition of "component."

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 (let alone 10 "assemblies"), will cause a cascading chain reaction that will upset the delicate balance that goes into the scoping, procurement, assembly, and quality and safety validation 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. DTSC needs to craft carefully and narrowly tailored regulations to guard against any such adverse consequences.

Turning back to the Revised Regulations' specific provisions, the DTSC's proposal to compel the redesign and remanufacture of up to ten (10) component parts at a time, including assemblies, 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 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 Revised Regulations as they now read.

At most, the final Regulations should authorize the DTSC to specify up to three (not 10) components - - not assemblies or subassemblies - - of engine/vehicle products for alternative analyses over any 4-year (not 3-year) time period. A minimum four-year lead-time 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 Revised 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 narrowing the definition of "component" to exclude assemblies and subassemblies, and without providing the requisite minimum four-year lead time period, the unreasonable weight and cost of the resulting regulatory burdens on the manufacturers and

assemblers of complex durable goods will cause the collapse of the DTSC's envisioned consumer products safety program.

**The Revised Regulations Should Not Apply  
To Service Parts For Existing Products**

The Revised Regulations have taken a significant step backwards in connection with the treatment of service parts necessary for the repair and refurbishment of products manufactured prior to such products' designation as a "priority product." Under the earlier draft of the Regulations, the term "manufacture" specifically excluded the following actions:

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

The Revised Regulations have eliminated those exclusions and safeguards for the repair of existing products. This will render the Revised Regulations wholly unworkable and unreasonable as applied to the manufacturers of complex durable goods. Accordingly, DTSC should restore those necessary exclusions.

More specifically, and as already noted, vehicles, engines and equipment are comprised of thousands of specialized components that are specifically designed and tailored to integrate with and fit into the fully-assembled complex product. Thus, the design, composition, shape, size, mechanics and weight of the components are all integral to the assembly and efficient operation of the type of vehicles, engine and equipment at issue. As a necessary result, any repair or replacement parts for previously manufactured vehicles, engines and equipment need to be identical in every material respect to the original components in order to avoid compromising the integrity and effective operation of the previously manufactured product. In addition, complex durable goods are specifically designed to last for many years, which necessarily requires that manufacturers maintain a full inventory of service parts for many years as well.

The net result is that in those instances where one or more (not more than 3) components of a complex durable good are designated as priority products and, as a consequence, reformulated and redesigned, the DTSC cannot mandate that those reconfigured components be utilized in the repair and refurbishment of previously manufactured goods. Those reformulated components necessarily will not have been designed to meet the unique design criteria of previously manufactured complex durable goods, are likely to impact the quality and viability of repairs, and, in all probability, will lead to a violation of the manufacturers' original warranty for the previously manufactured complex durable products.

For all these reasons, therefore, DTSC needs to restore the prior exemption afforded for the parts necessary to service and repair previously-manufactured complex durable goods.

### **The Proposed Criteria For Approval Of An Alternative Product Are Unreasonably Vague**

Under the “alternatives analysis” requirements that the DTSC is proposing, the responsible entity’s ultimate obligation is to fully evaluate “whether an alternative [to a priority product] exists that is functionally acceptable, technically feasible, and economically feasible.” (See, e.g., Revised Regulations, section 69505.6.) The Revised Regulations define those operative terms as follows:

“Functionally acceptable” means that an alternative product...performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

“Technically feasible” means that the technical knowledge, equipment, materials, and other resources available in the marketplace are expected to be sufficient to develop and implement an alternative product or replacement chemical.

“Economically feasible” means that an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.

All of the foregoing key “criteria” are unreasonably vague and ambiguous, and thus are inherently ill-suited to serve as the core benchmarks of the DTSC’s program. For example, each of the governing criteria could mean widely divergent things depending upon which entity is assessing the criteria. Consumers will have a very different view than the DTSC of what works “sufficiently well.” Manufacturers will have a different view than DTSC of whether technical resources are “sufficiently” available, and will most certainly have a very different view of what amounts to a “significant reduction” of their operating margins. In that regard, any regulatory program that is crafted to yield such disparate results depending on the eye of the beholder is a program that is inherently suspect as being void for vagueness.

Consequently, the Revised Regulations need to be further revised to set more objective criteria for the evaluation and comparison of alternative products and replacement chemicals. Otherwise, the DTSC’s program will be set up for myriad additional legal challenges from the very outset of its implementation.

### **The Expanded Focus On “Potential” Exposures And Impacts Should Be Deleted**

Similarly, the Revised Regulations’ criteria for identifying candidate chemicals and priority products and for fashioning regulatory responses have been amended in a manner that makes those criteria overly broad and, for all practical purposes, unmanageable. More specifically, the DTSC’s prior draft of the green chemistry regulations focused on a chemical’s

or product's "ability to cause" adverse impacts. Under the Revised Regulations, however, the proposed focus has expanded to a chemical's or product's "potential for" adverse impacts. In that regard, DTSC has added the word "potential" into the text of the Revised Regulations not less than sixty-five (65) times, and has included a new definition of the term "potential" to mean "reasonably foreseeable based on reliable information."

The net effect of expanding the focus of the Regulations from the "ability" of chemicals to cause adverse impacts to the "potential" for chemicals to cause adverse impacts is that the scope and breadth of the obligations under the Revised Regulations have become, in a very real sense, unlimited and therefore inherently unreasonable. Almost anything is "potentially" possible when assessing "potential" risks, perhaps constrained only by the power of imagination. Accordingly, imposing obligations on responsible entities to evaluate all "potential" exposures and adverse impacts of products and chemicals (as opposed to the product's actual "ability" to cause adverse impacts) is tantamount to the imposition of limitless obligations. That, in turn, creates impossible regulatory requirements, which, by definition, are invalid.

Accordingly, in order to avoid additional claims that its green chemistry regulations are overly broad and unreasonable, the DTSC should delete the numerous references to "potential" impacts and exposures in the Revised Regulations, and should return to the original text that focused on a product's actual "ability" to cause adverse impacts.

#### **Notice And Comment On All Alternatives Analyses Will Create Unreasonable Burdens**

The Revised Regulations include a notice and comment process with respect to every preliminary alternatives analysis report prepared by a responsible entity. As a consequence, in any final alternatives analysis report, the Revised Regulations require that the responsible entity "include a summary of the public comments submitted [regarding the preliminary AA] and a description as to how the comments are addressed in the [final] report or an explanation as to why the comments are not addressed in the AA Report." (See Revised Regulations, sections 69505.1(d) and 69505.7(i)(1).)

This aspect of the Revised Regulations seeks to impose on "responsible entities" obligations similar to those imposed on project proponents under the California Environmental Quality Act ("CEQA"). In that regard, CEQA's notice and comment requirements have proven to be unreasonably burdensome and cumbersome, and have not ensured that potential substantive environmental issues receive an open and objective review. Rather, the CEQA process has morphed into a strategic (and often anticompetitive) weapon that project opponents can launch to delay or significantly increase the costs of a development project. The same adverse consequences are likely to develop under the DTSC's proposed notice and comment process for alternatives analysis reports.

In addition, the notice and comment procedure that the DTSC has proposed is one that is typically undertaken by regulators, not regulated entities. The principles of regulatory

development, administrative law and due process all require that regulatory agencies provide notice and comment opportunities before they take any final administrative action. That notice and comment process, however, is completely out of place in the context of a regulated entity's efforts to comply with regulatory requirements. In that regard, DTSC personnel are presumably qualified to assess the preliminary AA reports that the DTSC is mandating be submitted without receiving the responsible entity's response to public comments filed with the DTSC. Imposing public notice and comment burdens on the regulated entity in this context is wholly unnecessary and will serve only to create additional unwarranted and unreasonable burdens, delays and costs on responsible entities. Accordingly, this notice and comment requirement, to the extent it imposes any obligations on responsible entities, should be deleted. Otherwise, the DTSC's program will again be subject to immediate challenge and potential invalidation.

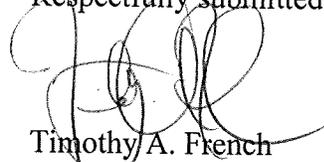
### **Conclusion**

The Revised Regulations are preempted, inherently unworkable and fundamentally illogical in the context of the complex durable goods manufactured, assembled and imported 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 engines and emissions-related equipment that EMA's members produce and distribute on a world-wide basis. DTSC also should make the other changes to the Revised Regulations as discussed herein to help ensure that the contemplated program does not collapse under its own weight.

As noted above, these comments are supplemental to EMA's initial comments (submitted in October) and to the comments that the Coalition has submitted, which sets of 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.

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

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February 28, 2013  
Page 12 of 12

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**EUROPEAN COMMISSION**  
 ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Internal Market for the Free Movement of Goods  
 Prevention of technical barriers

Brussels,  
 LK/BL - entr.c.3(2013)291386

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**E-MAIL**

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**Subject:** **G/TBT/N/USA/727/Add.3 – DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC) ON "SAFER CONSUMER PRODUCTS"**

**EU comments**

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**Message:**

Dear Sir or Madam

Please find attached the comments from the European Union on the above-mentioned notification.

Could you please acknowledge receipt of this e-mail? Thank you.

Yours faithfully

  
 Giuseppe Casella  
 Head of Unit

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**COMMENTS FROM THE EUROPEAN UNION CONCERNING  
NOTIFICATION G/TBT/N/USA/727/Add.3**

**DRAFT REGULATION OF THE CALIFORNIAN DEPARTMENT OF TOXIC SUBSTANCES CONTROL  
(DTSC) ON "SAFER CONSUMER PRODUCTS"**

The European Union (EU) would hereby like to submit comments on the latest revised version of the draft Regulation of the California Department of Toxic Substances Control (hereinafter "DTSC") on Safer Consumer Products, which was notified on 7 February 2013.

The EU regrets that DTSC has neither replied to the earlier comments submitted by the EU on 11 September 2012 and 21 December 2012, nor provided any explanations regarding if and how the EU's earlier comments have been taken into account or which changes in the last version of the draft Regulation are linked to the EU's earlier comments.

The EU also notes that the deadline for comments was determined for 28 February 2013, whereas the revised draft was notified on 7 February 2013.

The EU would like to refer to Article 2.9.4 of the TBT Agreement, which provides that Members shall "without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take these written comments and the results of these discussions into account." The TBT Committee agreed in this respect that the normal time for comments on notifications should be at least 60 days.

The EU will first provide general observations on the principles of the draft Regulation and then offer more detailed comments on the text itself.

**General Comments**

As already stated in its earlier comments, the EU fully shares the objectives of the draft Regulation, namely to achieve a high level of protection of human health and the environment by substituting the most hazardous chemicals with safer alternatives and adequately informing users about the risks from chemicals. To this effect, the EU has put into place, among others, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, and Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as "REACH" and "CLP" Regulations).

With regard to the main principles of the last version of the draft Regulation, the EU appreciates that one of its main concerns expressed in the earlier comments has been resolved, namely all requirements related to a highly specific accreditation and certification system for organisations and persons authorised to conduct alternatives assessments have been removed. The EU welcomes this improvement.

However, the two other main concerns still remain valid and will be explained in more detail below:

- potential for unequal treatment of economic operators,
  - complexity of the proposed alternatives assessment procedure and high administrative burdens related to its implementation raising concerns about their compatibility with Article 5.1.2 of the TBT Agreement.
1. Several provisions of the draft Regulation still have the potential for discriminatory effects among the so-called "responsible entities" (i.e. manufacturers, importers, assemblers, or retailers), both at the beginning and the end of the process.

For example, under § 69501.4 (a)(1) (C) and (D) of the draft Regulation, DTSC can request a responsible entity or a chemical manufacturer or importer to make existing information available to DTSC within a specified time frame, or even oblige an economic operator to generate new information and provide it to DTSC. Failure to do so results in the responsible entity being "black-listed" on the 'Response Status List' of DTSC in accordance with § 69501.4 (c). However, a responsible entity not known to DTSC or not having been asked to provide information will not appear on this list, without the stigma of having failed to respond to requests from DTSC. Hence, solely the fact of being known or not known to DTSC will potentially lead to discriminatory consequences for responsible entities.

According to § 69503.7 responsible entities must submit priority product notifications, following the listing of the priority products concerned by DTSC. However, if companies do not identify their products themselves, they will not be known to DTSC and will be spared the burdensome consequences of conducting an alternatives analysis and of implementing regulatory response(s). The EU would like to ask how DTSC will ensure that all duty holders will be treated equally given that at the time of listing priority products, DTSC will not have a complete market overview.

According to § 69505.4 (d), a responsible entity may fulfil its requirements to conduct an alternatives analysis (hereinafter "AA") by submitting to DTSC a report for a previously completed AA for the priority product. There is no clear requirement that this can only be done with the agreement of the entity that did submit the previous AA (at least for a certain period of data protection). It is true that in the latest version DTSC has added that *'the previously completed AA may be either an AA conducted or obtained by the responsible entity or a publicly available AA'*. However, given that all AAs submitted to DTSC will eventually be made publicly available, it is still not clear that the consent of the company having prepared the previous AA is required for its re-use - consequently, the 2<sup>nd</sup> entity will not have to sustain the costs and efforts related to the AA, which were born in full by the 1<sup>st</sup> entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

After having conducted the alternatives analysis, different responsible entities marketing the same (or very similar) priority product(s) with the same chemicals of concern, can come to very different results – some being able to replace the priority product or chemical of concern, while others might not and hence propose different 'regulatory responses'. Whilst DTSC will ultimately decide on the

regulatory responses, it is not clear from the draft Regulation that DTSC will actually require in such circumstances that all entities have to replace the product or chemical of concern, or whether DTSC will indeed impose one or several regulatory response(s), which could again be different for the responsible entities.

Lastly, some of the regulatory responses that DTSC can impose also have the potential of having very different consequences for responsible entities, in particular when these are small or medium-sized enterprises (SME) or located outside California. For example, an SME (or an importer on behalf of an SME manufacturer outside California) selling only relatively few priority products will never be able to set up the very demanding and costly End-of-Life Management Requirements described under § 69506.7, whilst this might well be feasible for a big company. Imposing this regulatory response would, *de facto*, amount to a ban for the SME producer, whilst this would not be so for a big company producer. Likewise, DTSC can impose the regulatory response to fund research and development projects for the advancement of Green Chemistry and Green Engineering (§ 69506.8), but there is no indication as to which amount(s) will be involved. In order to avoid disadvantages for SMEs, there should preferably be a link with a certain percentage of the turnover made with the priority product in question.

2. The EU would like to elaborate below on the provisions of the draft Regulation related to the alternatives assessment procedure and the administrative burdens related to the implementation, with respect to which it has concerns about their compatibility with Article 5.1.2 of the TBT Agreement.

First of all, the EU would like to note that the US Government is making strong efforts in recent years to reduce and avoid administrative burdens for businesses. Accordingly, the Californian proposal seems to be at odds with the US 'smart regulation' policies and principles. In particular, the EU would like to refer to Executive Order 13563 of January 18, 2011 on Improving Regulation and Regulatory Review, which notably provides that the US regulatory system must: promote predictability and reduce uncertainty; identify and use the best, most innovative, and least burdensome tools for achieving regulatory ends; take into account benefits and costs, both quantitative and qualitative; ensure that regulations are accessible, consistent, written in plain language, and easy to understand and measure, and seek to improve, the actual results of regulatory requirements.

Many of these points are not respected by DTSC's draft Regulation. The draft text is very complicated to read and understand, it clearly does not use the least burdensome tools and it is doubtful that it will achieve its objectives.

Even though DTSC has made certain changes in the latest draft that intend to simplify the alternatives analysis (AA) as described in Article 5, the various procedures involved remain heavily bureaucratic (with a plethora of different notifications or reports to be submitted), and a full AA remains excessively complex as the range of factors to be analysed is extremely broad and will require huge amounts of data that might be very difficult to obtain. In particular, responsible entities that are SMEs might well not be able to find all relevant data, not even with the help of outside consultants – or, if so, only at very high cost compared to the company's financial means. It is regrettable that in its analysis of

economic impacts DTSC has not actually analysed a few case studies (e.g. a simple case of a chemical mixture and a more complex case of an article composed of many components) to actually demonstrate that the prescribed AA is feasible within the given amount of time and at what costs<sup>1</sup> (even leaving aside the actual costs for substituting the chemical of concern). This type of analysis for processes and procedures was conducted by the EU before REACH was adopted - in fact, this had been strongly called for by economic operators and third countries, including the US, and this has ultimately helped to modify a number of provisions in REACH in comparison with how they were originally envisaged<sup>2</sup>. The EU would therefore call on DTSC to reflect on ways on how the AA can be simplified, for example in the guidance that is to be developed in accordance with § 69505, or by designating a more limited and specific range of parameters to be analysed when listing a priority product and chemical(s) of concern according to § 69503.4.

The numerous (and in themselves already rather complex) notifications and reports to be submitted by the responsible entities to DTSC, their evaluation by DTSC (within rather short periods of time), the various notices of approval or deficiencies, further submissions and updates of already submitted AA reports, as well as possibilities for administrative disputes etc. could often be duplicative and bear the risk that DTSC might quickly become overwhelmed by the programme. For example, if, as projected, the first list of priority products contains 5 products and each of these is marketed in California by 10 responsible entities, DTSC would have to deal with 50 product notifications (a certain % of which might require follow-up), up to 50 preliminary AA reports (again a certain % of which might require follow-up actions), and up to 50 final AA reports, each probably containing several hundred pages and complex information, many being different from each other in terms of content and quality, all to be analysed by DTSC within 60 days and, if necessary followed-up with complementary submissions by the responsible entities concerned. In parallel, DTSC will have to continue the (also rather demanding) work of identifying further priority products and chemicals of concern and many other activities.

The EU would like to ask why DTSC has not considered an alternative way for crafting the process, which would avoid duplicative work for both responsible entities and DTSC and correspond more to the Restrictions Title under REACH or the Canadian Chemicals Management Plan. For example, after designating a priority product and its chemical(s) of concern and thus requiring responsible entities to notify the priority products, DTSC could then call for submission of all relevant data by a certain date from these responsible entities and all other stakeholders (including the NGO Community) and conduct itself the alternatives analysis (either in house, with the help of the Green Ribbon Science Panel, or an outside assessor – in the latter case, costs could be split among all responsible entities having been identified by the priority product notification process according to their turnover with the priority product), and then determine directly a

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<sup>1</sup> In fact, in the earlier Economic and Fiscal Impact Statement, DTSC merely stated on pages 4 and 5 that costs could vary between a few thousand dollars and hundreds of thousands of dollars, which is not very informative. Analysis of a few real case studies as for example conducted in the electronics industry and/or the US EPA Design for the Environment Programme would probably have provided more concrete estimates, both for costs and the necessary time.

<sup>2</sup> Further information is available at:

[http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm)

regulatory response. This could well be more efficient in terms of resources required and the necessary time for implementation and would ensure equal treatment of all responsible entities. In fact, in order to be able to review AAs prepared by responsible entities, decide on their being appropriate (as required by § 69505.8), and decide on the Regulatory Response in each case in line with § 69506, DTSC will in any case need the expertise required for conducting AAs. By having to conduct and review multiple AAs for the same (or similar) priority product(s) with potentially different outcomes for each of them, the overall workload is multiplied compared to one single analysis. Such an alternative has, unfortunately, not been evaluated under section D of the Economic and Fiscal Impact Statement, where the alternatives considered are all based on the concept that the AA has to be conducted by responsible entities, while nothing in Assembly Bill 1879 on which this draft Regulation is based actually so requires.

### **Specific comments:**

In the following, the EU will comment on some more specific issues in the various sections of the draft Regulation in their order of appearance in the draft text (page numbers refer to the version with the changes marked).

### **Article 1:**

#### **§ 69501.1. Definitions**

Page 7, lines 32-38: It seems highly unlikely that a chemical substance could have the adverse impacts mentioned under points (A) (B), or (D). In particular, (A) or (D) could only materialise if the chemical was intentionally used for that purpose (e.g. asphalt or concrete).

Page 10, lines 12 to 16: The definition of "chemical" is rather specific and not in line with international standards such as "substance" and "mixture" defined in the UN Globally Harmonised System (GHS). This can lead to confusion and clarity could be increased by specifying that a chemical is either a substance or a mixture and then using the definitions of the UN GHS for these two terms.

Page 10, lines 21 to 39: The definition for the term "molecular identity" is somewhat confusing and includes parameters that go well beyond molecular characteristics. It might be better to use the term 'substance identity'.

Page 13, lines 32 to 35: It is unclear why there is an exemption for an 'Importer' who imports a product solely for use in that person's workplace (*underlining added*). This would allow companies to import products that could lead to serious risks for workers. Is this really the intention? Or should "workplace" not be rather replaced with 'private use', i.e. only exempting import by consumers for "own use"?

Page 17, lines 37 to 39: The final part of the definition of a "retailer" is somewhat confusing. According to the Health and Safety Code in California, the term 'Consumer Product' includes also products sold to professional users. A retailer selling such a product to professionals would, therefore, also be covered by the rules of the Regulation, whilst this definition seems to suggest that this is not actually the case.

### **§ 69501.2. Duty to comply and Consequences of Non-Compliance**

Page 21, lines 27-30: These provisions create again the potential for discriminatory treatment. By indicating on the 'Failure to Comply List' the names of only some products that are known to contain a component which is a priority product (and for which the manufacturer has not complied with his obligations), but not for all products containing the component, severe disadvantage will result for manufacturers of such known products, compared to those, which are not known to DTSC and will, therefore, not appear on the 'Failure to Comply List', even though their manufacturers are in the same non-compliance situation as those of the 'known' products.

### **§ 69501.3. Information Submission and Retention Requirements**

Page 22, lines 22 to 24: when and where will the "manner and electronic format" for data submission be specified? Will DTSC consider using internationally recognised formats such as International Uniform Chemical Information Database (IUCLID)?

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

As already commented above, the provisions of this paragraph (in particular on page 23, lines 22 to 28) lead to potentially discriminatory treatment between responsible entities solely due to whether they are known to DTSC and receive requests for input or not. An arbitrary selection of economic operators for soliciting information would create obligations for some but not for others. The EU would like to seek clarification on whether this provision includes also manufacturers in 3<sup>rd</sup> countries and how DTSC will ensure that they have the same possibilities to act as manufacturers in the US, given that they might not be aware of the obligations under the Regulation and correspondence/communication might not be as easy as with manufacturers based in California (or in the US). In addition, the public listing of companies for having failed to respond to requests from DTSC for information even before a decision has been taken on whether or not a product and/or chemical of concern will be selected for prioritisation is not justified. Rather than contacting individual companies with information requests and denouncing companies for not having submitted information at this stage of the process, DTSC might wish to limit the information requests to general calls as specified in subsection (b)(2) and then publish the names of those companies that have co-operated and responded. This would then be a reward and incentive for companies to participate in line with what is already foreseen in section (d).

Page 23, lines 29 to 31: It is unclear why these new provisions have been added. What is their intention?

Page 24, lines 23 to 24: How will the quality and integrity of voluntary AAs be evaluated? Whilst a detailed process is laid out in § 6505.2 to 5 for responsible entities to conduct a "mandatory" AA and in §69505.6 for DTSC to verify the results of a "mandatory" AA, there seems to be no such verification for voluntary AAs.

### **§ 69501.5. Availability of Information on the Department's Website**

This paragraph sets out a long list of information to be made available on DTSC's website, much of which will require almost constant updating. As this will be very resource-intensive and bears a high risk of displaying inaccurate information, DTSC might wish to consider prioritisation of a more selected list of information for publication. Has DTSC ensured that the publication of the names of individual persons (e.g. as required by subsection (b)(3)(D) the identity of the person who will fulfil the requirements of Article 5) is compatible with rules on the protection of personal data?

### **§ 69502.2. Process for Identifying Candidate Chemicals**

Page 27, line 35. The EU supports that the draft Regulation refers to substances classified in the EU and also to other recognised classifications. The reference to the classifications in the CLP Regulation is correct as such, except that in line 35 the text '**(European Commission)**' is wrong – the correct form is indeed '**(EC)**'.

Likewise in line 39, the text '**(European Commission)**' should be replaced with '**(EC)**'.

Idem on page 28 in lines 14 and 19.

### **§ 69503.5. Priority Products List**

Page 38, lines 5 to 7: How will priority products be identified in the list? By (more) general descriptors of purpose and function, or by individual brand names? It could be very important for companies to know this in order to assess whether their products are concerned or not.

Page 38, lines 8 to 10: As commented before, the listing of only known assembled products that contain a component identified as priority product creates a significant disadvantage for such products compared to others, which might also contain the component but are not known to DTSC.

Page 43, lines 11-13: Can DTSC provide an estimate of how many chemicals of concern will be identified in the initial list as the reason for listing the (up to five) priority products? The draft Regulation only states that DTSC '*may identify more than one chemical of concern for each listed product*'.

### **§ 69503.7. Priority Product Notifications**

The EU would be interested to learn how DTSC will ensure that all responsible entities concerned will comply with their obligations under this paragraph, which is also the basis for all subsequent obligations. Point (b) (page 44, lines 9-10) sets out that a responsible entity that does not notify is in non-compliance, but does not describe any steps that DTSC will take in order to determine cases of non-compliance. This is actually not set out anywhere in the draft Regulation, nor in the Initial Statement of Reasons.

Page 43, lines 33-36: According to this provision, companies could start placing a priority product with chemicals of concern into the stream of commerce in California at any time, even after listing of the product-chemical combination in the priority product list. The only requirement is that they then submit a priority product notification and then conduct an AA. This could, therefore, also happen after the timeframe during which AAs for all products already on the market have been

completed, and DTSC might already have decided on a regulatory response (which could be a ban or a restriction). It seems illogic to allow in such a situation that the same priority product that has already been subject to an AA and regulatory response decision can be placed on the market again – and the entire process would have to start all over again. It should, therefore, be specified that any new entrant into the market would have to comply with the regulatory response already established before for the priority product in question.

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

As already pointed out above, and despite some modifications made by DTSC in this version of the draft Regulation compared to earlier ones, the requirements for conducting an alternatives analysis (AA) are highly complex, both technically/content-wise and administratively with multiple notifications and submissions of reports, each of which will require reactions by DTSC and the submitting entities. The time periods foreseen for completing the various steps seem short compared to the tasks to be accomplished, in particular for preparing a final AA report (12 months) and for DTSC to review and react to the final report (60 days). For reasons of comparison, the EU would like to inform the US authorities that under REACH the normal time frame for preparing a request for authorisation for continued use of a substance on Annex XIV of REACH (which includes an analysis to demonstrate that there is no suitable alternative for the substance concerned) is between 18 and 24 months (while the range of parameters to be analysed is substantially narrower than in the draft Regulation of California), whilst the European Chemicals Agency (ECHA) has then 1 year to provide the opinions of its Risk Assessment Committee and its Socio-Economic Analysis Committee, before the Commission takes a formal decision on whether or not an authorisation for continued use of a substance can be granted.

Page 46, lines 25-28: The EU observes that it will be absolutely indispensable that California develops guidance for the implementation of the very demanding obligations that companies have to comply with under the draft Regulation. In particular for small and medium size companies it will be extremely difficult to conduct the required alternatives analyses – even with guidance. Third country authorities and trade associations should be involved in the process for the development of such guidance documents. The EU also offers to make available the very extensive guidance that has been developed for the purposes of REACH and CLP, which could be a good starting point for the authorities in California.

Page 46, lines 29-32: Is DTSC aware of such sample AAs as mentioned here? If so, do they correspond to all the requirements in the Regulation and were they established within the same timeframes?

Page 47, lines 37-40: Same comment as above concerning page 43: The provisions are somewhat confusing as they seem to allow the placing on the market in California of new priority product(s) containing chemical(s) of concern (subject to the conduct of an AA within a certain deadline), even after the products have been listed, all responsible entities having already conducted their AA and DTSC having already imposed a regulatory response (which might actually be a ban or an obligation to replace a chemical of concern). This possibility should, therefore, be limited until such time that DTSC has imposed a regulatory response for a given priority product after

which any entity wishing to market a new product would have to comply with the regulatory response. It seems not to be efficient to require another AA to be conducted then. Once the process of an AA and regulatory response decision is completed, it should not be possible to place a product containing the same chemicals on the market for the first time – instead the decided regulatory response should be complied with by any new market entrant.

Page 48, line 27-31: This provision specifies that '*Failure of the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request*'. However, what does this mean for a responsible entity having submitted a request without response within 30 days? It would need to know according to which timeline it has to prepare the AA.

Page 49, lines 27-41: It seems excessive to require that responsible entities must summarise in their AA reports how they have made use of information made available on DTSC's website

Page 50, lines 8-13: Again, the draft Regulation states that a failure by DTSC to decide on the compliance status of an AA report within the given time frame, does not mean that the AA report is considered compliant. However, what does this mean for a responsible entity having prepared an AA? It will need to know what further action, if any, will actually be necessary.

Page 52, lines 6-8: While the EU understands that DTSC has introduced various 'removal notifications', as a possible substitute to conducting an AA, what is required here in terms of information is almost as demanding as what is required in an AA itself.

Page 55, lines 12-30. DTSC has introduced new provisions that allow responsible entities to submit abridged AA reports if they conclude during the preliminary AA that there are no alternatives to a priority product – chemical of concern combination. Compared to a full AA report, an abridged AA seems less resource intensive. Consequently, responsible entities now actually have an incentive to conclude during the preliminary AA that no alternatives are available, which seems to be counter-intuitive to the intention that DTSC pursues with this draft Regulation.

Page 57, lines 6-12: As already commented above, the provision to allow a responsible entity to fulfil its requirements to conduct an alternatives analysis (AA) by submitting to DTSC a report for a previously completed AA for the Priority Product is problematic. There is no clear requirement that this can only be done with the agreement of the entity that did submit the previous AA – now available in the public domain (at least for a certain period of data protection) as otherwise the second entity will not have to sustain the costs and efforts related to the AA, which were born in full by the first entity. So unless the entities are the same or there is an agreement between them to allow using the previous AA, the entity having conducted the first AA will be at a disadvantage.

Page 64, line 21 to page 65, line 33: The EU would comment that while DTSC has made efforts to reduce the workload related to an AA, the range of factors to be analysed during the second step of the AA is extremely broad, which makes it very

difficult to conduct the analyses within reasonable cost and time. For many parameters it will be virtually impossible to find (or just model) the required data – for example, it is totally unclear what is meant by 'Multimedia Life Cycle Impacts', or how a company could assess, quantify and monetize (which is notoriously difficult) the public health and environmental costs, or the costs to governmental agencies and non-profit organisations. This will be even more complicated if a manufacturer is located in a third country and hence clearly less familiar with conditions and government structures in California. The EU notes that in the framework of the Economic and Fiscal Impact Statement DTSC has not documented any feasibility analysis or "beta-testing" to examine whether the required work can be conducted at all, to estimate the costs and necessary timeframe for conducting an AA and whether these costs are proportionate. The EU would also like to recall that in the development of the REACH Regulation, the Commission, the Member States and industry conducted numerous feasibility experiments – the so called Strategic Partnership on Reach Testing (SPORT) and Piloting REACH for Downstream Use and Communication in Europe (PRODUCE)<sup>3</sup>, the results of which led to significant changes between initial drafts and the final Regulation in the light of feasibility and proportionality considerations.

Page 69, lines 35-40: It is unclear how a responsible entity could comply with this obligation. If certain information is not available, it is difficult to assess whether it would meet the criteria listed under points (A) and (B).

Page 71, line 1 should read correctly 'EC number' and not 'European Commission Number'.

Page 72, line 28 to page 75, line 6: As already commented before, the time frame for DTSC to review an AA report (60 days) and also the time frame for responsible entities to redress deficiencies (60 days) seem excessively short against the background of the complexity of the work required.

## **Article 6. Regulatory Responses**

As a general question, what will DTSC do in the case of diverging or conflicting results of alternatives assessments for the same/similar products and chemical(s) of concern? Given that many different actors will conduct AAs the risk that there will be diverging results with regard to regulatory responses will be quite high. Does § 69506 have to be understood in the sense that DTSC will ultimately impose the same regulatory response on all responsible entities or will there be different ones for different entities? What will DTSC do when some responsible entities conclude in their AAs that alternatives are available for a given priority product – chemical of concern combination, while other responsible entities conclude for the same priority product – chemical of concern combination that this is not the case?

Page 79, lines 25-42 again entails a significant risk of discriminatory treatment between responsible entities. If requests for additional information are made, they should concern all entities and not only individual ones. If one of them has already provided the information, DTSC could increase efficiency by using it and require all

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<sup>3</sup> Further information is available at:

[http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/archives/trial-runs/index_en.htm)

others to participate in the costs of the first one for generating the information, rather than requiring them to produce the same information again.

Page 81, lines 7-19: It is not clear why DTSC wishes to operate with individual notifications to responsible entities to establish product sales prohibitions. Would it not be more efficient and less discriminatory, if, instead, DTSC established a horizontal rule prohibiting the product (or chemical of concern) in general and for all entities wishing to place it on the market in California?

Page 83, line 20 to page 86, line 7: The regulatory response to set up a comprehensive end-of-life management programme (including comprehensive financial guarantees, burdensome procedures with public consultation to develop such a programme and burdensome yearly reporting) seems impossible to meet for individual companies – in particular for manufacturers of products that are SMEs and/or located in third countries - and can probably only be achieved if the DTSC establishes a rule applicable to (a range) of products that would apply to all responsible entities to create this jointly. Again, the EU would like to know whether the DTSC has undertaken any feasibility studies with regard to this particular regulatory response, in particular for SMEs. In the light of the high costs involved, this regulatory response could amount to a disguised ban on marketing the product in California.

Page 86, lines 12-22: The EU would like to know according to which criteria the obligation to fund 'Green Chemistry' Research will be put into practice. How will the amounts be determined that a responsible entity will have to provide? As a share/percentage of overall sales? How will the DTSC avoid discriminatory treatment of different responsible entities?

Page 88, lines 16-24: Again, this subsection implies that different responsible entities will get different regulatory responses imposed for the same (or similar) priority product(s). It would seem more logical that DTSC informs all retailers and publishes general rules about one identical regulatory response applicable to all responsible entities in a non-discriminatory way.

Page 89, lines 5-36: These subsections establish burdensome reporting requirements for responsible entities and even more so for DTSC itself, as the number of products and regulatory responses concerned could easily run into the hundreds after a few years and would grow continuously over time.

The EU would appreciate if the US authorities would take into account the above comments and looks forward to receiving a reply to these comments.

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February 28, 2013

Ms. Krysia Von Burg  
Department of Toxic Substances Control  
P.O. Box 806  
Sacramento, CA 95812-0806  
U.S.A.

Re: Comments of the European Semiconductor Industry Association on Safer  
Consumer Products Proposed Regulations

Dear Ms. Von Burg:

On behalf of the European Semiconductor Industry Association (ESIA) we are writing to provide our views on the "Safer Consumer Products" proposal of the California Department of Toxic Substances Control (DTSC), published at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-30-Day-Regs-Text.pdf> (Department Reference Number: R-2011-02; Office of Administrative Law Notice File Number: Z-2012-0717-04).

European Semiconductor Industry Association is the trade association of the European based semiconductor industry. More information about our organization can be found at <https://www.eeca.eu/esia>

We are writing in support of the comments filed on February 28, 2013 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 ESIA 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 are flawed in several respects. We believe that the proposal, if finalized, will be overly burdensome to all industry in the supply chain. Furthermore, several requirements in the proposal are not harmonized with other product stewardship regimes currently in effect (e.g. EU RoHS). The timelines in the proposal are not feasible given the complex supply chains of multicomponent products. The proposal does not provide adequate protection for proprietary information, and the approach to confidential business information is inconsistent with current practices. Finally, we believe that this proposal will penalize innovators by imposing excessive requirements.

This proposal also has some issues from a procedural perspective. The proposal would create a regulation with a global impact without providing due time for comments and determinations of impact and feasibility from companies and industry groups around the world. In addition, because the proposal is lacking some key details (e.g., product lists, chemicals lists), it is impossible for affected companies to assess the total impact. In addition, the proposal does not

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provide for an adequate implementation period of the process prior to compliance requirements taking effect.

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

Yours Sincerely,

Hendrik Abma  
ESIA Director General

**To:** Jeff Wong, Ph.D.  
Office of the Chief Scientist  
Department of Toxic Substances Control

**From:** William H. Farland, Ph.D., ATS  
Scientific Peer Reviewer



**Date:** March 4, 2013

**Subject:** Scientific Peer Review for Safer Consumer Products Regulations

Thank you for the opportunity to serve as a scientific peer reviewer on the latest version of the Safer Consumer Products Regulations. I have completed my review which is structured around the scientific issues and peer review points that you provided. My detailed comments are attached.

My detailed comments notwithstanding, I am of the opinion that the proposed rule is based upon sound scientific knowledge, methods and practices. The Regulations continue to rely heavily on the work of others who have constructed lists of potentially hazardous substances which, for the most part, have relied on public processes and scientific peer review in their construction. The addition of lists from authoritative organizations will only strengthen the basis for State decision-making. The use of the term “candidate chemical” for the large number of chemicals that will comprise the “list of lists” is more scientifically defensible than call them “Chemicals of Concern” from the outset. “Concern” needs to be raised in the context of the product-chemical combination. The evaluation criteria for prioritizing the product-chemical combinations are robust and comprehensive. As such, they provide a reasonable basis for identifying all types of consumer products as potential Priority Products. The basis will still require significant scientific judgment but the clarification in the current version of the regulations to define “potential” effects or exposures as “reasonably foreseeable based on reliable information” will help in this context. I believe that the use of the “Practical Quantitation Limit (PQL)” is also an improvement for establishing an Alternatives Analysis Threshold. Finally, as discussed in my previous review, the discussion of what constitutes “adverse” continues to need further clarification. Slight changes to the use of “impact” versus “effect” in the proposed language of the regulation have done nothing to bring about this clarification.

Thank you again for the opportunity to participate in the scientific peer review of these proposed regulations. Feel free to contact me if you have questions regarding the attached detailed comments.

**Review Topic: The use of the chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Candidate Chemicals list.**

**Comment:**

As indicated earlier, it is my opinion that the use of chemical lists developed by “authoritative bodies” in California as well as elsewhere in the US and internationally is a scientifically defensible approach to identifying “Candidate Chemicals”. Each of the lists was the product of a rigorous process for determining criteria for inclusion and all have undergone independent peer review at the process level if not at the individual listing step. This point was well made in the “Initial Statement of Reasons” (ISOR) document where individual lists, their processes and scientific integrity are described. While each list will have its own criteria and listing thresholds, in the aggregate, they produce a list of chemicals that embody the hazard traits or chemical characteristics described in the regulation. Originally, the chemicals identified in subsection (a)(2) were identified as Chemicals of Concern (COCs). I believe that the response to comments and the change to call these “Candidate Chemicals” is more consistent with the fact that additional analysis will be required in order to determine whether their presence in a product raises a “concern”. Because these chemical lists were originally generated for a specific purpose (monitoring or reducing exposure/contamination), the Department is relying on the authoritative organization’s determination regarding chemicals exhibiting a hazard trait to be listed. Further analysis will determine which of the traits may be exhibited under particular product chemical combinations and specific exposure scenarios and therefore, when a chemical may be of concern.

The revised regulations include the following two additional lists from authoritative organizations to the list of lists for the initial Candidate Chemicals list:

1. Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.
2. Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals in addition to the section 303(c) chemicals.

It has been determined that these lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically. For these reasons, I see no problem with adding these lists to the list of lists. I do, however, question why the addition is limited to chemicals classified as Category 1 respiratory sensitizers when the same Regulation (EU Regulation 1272/2008) which has been in force since January, 2009 also includes a list of Category 1 skin sensitizers. Chemicals in this category meet the criteria of either having evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons or if there are positive results from appropriate animal testing. Chapter 54 (Section 69403.2) lists dermatotoxicity as one of the “Other Toxicological Hazard Traits” under Article 3. Sensitization is included as one of the toxicological endpoints in determining

dermatotoxicity. Therefore, it would seem prudent to not limit the addition to the list of respiratory sensitizers from the EU Regulation.

The regulation provides for the opportunity to add or remove chemicals from the list as new information relating to hazard traits becomes available. This opportunity includes a public notice and comment process which allows for broad based scientific input. This may be important for some future listing decisions because of the infrequency of updating of individual lists mentioned in the regulations and the evolution of the testing and assessment process.

**Review Topic: Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.**

**Comment:**

The regulation has provided a scientifically sound approach to prioritizing product-chemical combinations to identify consumer products containing Candidate Chemicals as potential Priority Products. To be considered a Priority Product, a product-chemical combination must meet both of the following criteria:

- (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts. In addition, it will consider waste and end-of-life effects in reaching this conclusion. The decision shall also consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts, potential exposures, and potential adverse waste and end-of-life effects. A further criterion to be considered is “the scope of other California State and federal laws and applicable treaties or international agreements with the force of domestic law under which the product or the Candidate Chemical(s) in the product is/are regulated and the extent to which these other regulatory requirements address, and provide adequate protections with respect to the same potential adverse impacts and potential exposure pathways, and adverse waste and end-of-life effects, that are under consideration as a basis for the product-chemical combination being listed as a Priority Product.” In this way, if a product is regulated by another entity with respect to the same potential adverse impacts and potential exposure pathways, and potential adverse waste and end-of-life effects, a listing decision is made under the regulation only if there is a determination that the listing would “meaningfully enhance protection of public health and/or the environment with respect to the potential adverse impacts and/or exposure pathways that are the basis for the listing.” In addition, the regulation allows consideration as to whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible.

As stated above, the regulations require consideration of information from both candidate chemicals and consumer products in combination. Evaluating and examining the information

from both, based on the availability of information to inform such judgments, will allow for flexible decision-making regarding which of the products should be listed as Priority Products. Because the decision-making process to designate a product as “high priority” is based on a variety of information and a narrative approach, DTSC has continued to use a narrative approach to describing its priority setting decisions rather than a quantitative weighting scheme. This seems like a sound decision given the typical available information and the differences one would see from product to product. As indicated in section 69503.3, decision-makers will use a wide-range of available information to consider and evaluate the potential adverse impacts and widespread exposure. Given the broad range of characteristics related to adverse impact and exposure parameters specified for evaluation over the lifecycle of the product within the regulation, this approach seems comprehensive, scientifically-sound and should be applicable to a wide range of products.

In expressing its intent in the revised regulations to consider “potential” for adverse impacts or wide-spread exposure rather than using the term “ability to” cause, the DTSC is clearer in its position that the impacts and exposure are “reasonably foreseeable” rather than simply hypothetical, given available information. This is an important distinction in establishing the criteria for listing Priority Products.

**Review topic: The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products are scientifically understood and practical.**

**Comment:**

In the revised proposed regulations, the Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the listed chemicals solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient.

The regulations specify the information that must be included in an Alternatives Analysis Threshold Exemption Notification, including the source of the contaminant COC(s). The notification must identify the PQL(s) for the COC(s) and the methods used to determine the PQL(s). The use of the PQL is standard practice in environmental regulations and laboratory analysis. This level is defined as a point where a signal can be quantified with statistical rigor. EPA has routinely used the PQL to estimate or evaluate the minimum concentration at which most laboratories can be expected to reliably measure a specific chemical contaminant during day-to-day analyses. This approach is scientifically defensible and understandable by the analytic community.

One issue that needs mention is that improved analytical performance (and hence, possible reduction of the PQL) may be suggested by lower detection limits from new methods. The existence of new methods with lower detection limits may not directly translate to improved analytical performance until sufficient experience is gained with the method and adoption is widespread. Since it will be incumbent on the submitter to justify the PQL selected for the COC(s) contained in the Priority Product, changes to PQL’s in individual chemical candidates may be seen over time. These will need to be considered at the time of review of the notification.

**Review Topic: The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.**

**Comment:**

The regulation is clear in its intent to protect consumers from the hazardous components of consumer products. In this context, avoiding “adverse” impacts/effects is easily understandable. In the scientific or toxicological definition of adverse, it is less clear. I addressed this issue in detail in previous review comments. Certain endpoints from toxicological testing which are used to determine hazard based on animal studies or high level exposures need to be viewed carefully as to whether these constitute “adverse” effects in the context of human hazard. Issues discussed in this regard have to do with what constitutes an “adverse” versus an “adaptive” response to the exposure. While these issues will clearly need to be addressed in order to make a scientifically defensible case for the potential “adverse impacts” of product-chemical combinations, the closest statement I can find in the regulation is that “The Department shall consider the extent and quality of information that is available to substantiate the existence or absence of potential adverse impacts...” While this statement may be reassuring to some, it is neither indicative of the difficulty nor explicit about role that scientific judgment will need to play in many of these decisions.

Of a less serious nature is the general use of impact and effect interchangeably. There appears to be no convention as to when one term is chosen over the other. In the current draft, impact has been changed to effect in a number of instances but there does not seem an obvious rationale for doing this. In general usage, “impact” is considered a weak alternative to “effect.” The definition given for “impact” does not address a difference. Unless a rationale for the use is presented, it might be better to choose one or the other with “effect” being my preference.



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February 27, 2013

**Via Electronic Mail:** [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**Via U.S. Mail**

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

**Re: Comments on the Revised *Safer Consumer Product Alternatives*  
Proposed Regulations**

Dear Ms. Von Burg:

On behalf of the Fashion Jewelry and Accessories Trade Association (“FJATA”), we appreciate this opportunity to submit comments in response to the California Department of Toxic Substances Control’s (DTSC) *Safer Consumer Product Alternatives* (SCPA) proposed regulations, a revised version of which was published on January 29, 2013. The proposed regulations are intended to implement Article 14 of chapter 6.5, division 20, of the Health and Safety (H&S) Code (hereinafter, “the Green Chemistry Initiative” or GCI).

FJATA is the major trade association representing companies that manufacture or distribute fashion jewelry in the United States. FJATA’s membership has a strong commitment to consumer safety. Most of FJATA’s members are small businesses.<sup>1</sup>

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<sup>1</sup> Fashion jewelry, like fine jewelry, includes bracelets, charms, earrings, necklaces, pins, rings, and other fashion accessories principally intended to be worn as an item of personal ornamentation. Styles are many and varied, and change multiple with fashion trends. Numerous materials may be used in jewelry, including metal (often plated with gold or silver), plastic, enamels, paint, wood, seeds, textiles, and other materials. Fine jewelry may also include a mix of materials. Fashion jewelry suppliers typically offer many different styles in small lots.

(continued ...)

FJATA has closely followed the development of the implementing regulations for the GCI, and believes that the current iteration of the proposed regulations will offer limited, if any, benefits as compared to the extraordinary burdens involved. Moreover, these regulations are likely to have a substantial adverse impact on small businesses because of the lack of flexibility, onerous administrative requirements, and duplication of existing regulations and requirements. In this regard, FJATA supports the comments made by the Green Chemistry Coalition. In addition to these overarching objections to the SCPA proposed regulations, FJATA offers below comments on specific provisions. In particular, FJATA submits that DTSC should: 1) adopt a general *de minimis* threshold for both intentionally added components and contaminants; 2) commit to avoiding duplication by adopting new requirements on jewelry, which is already regulated under existing federal and state laws, as well as enforcement mechanisms designed to protect the public health; 3) clarify that the trustworthiness of a reviewer for purposes of determining whether data or information is “reliable information” is based exclusively only on the credentials and qualifications of the reviewer; and 4) address the potential for confusion in its definition of a “manufacturer” due to customer specifications. Each of these comments is discussed in detail below.

#### **I. Eliminate the Practical Quantitation Limit and Adopt a *De Minimis* Threshold**

FJATA urges DTSC to abandon the Practical Quantitation Limit approach and reestablish a general *de minimis* threshold for both intentionally added components and unintentional contaminants. Without such a threshold, the program will be unworkable. Throughout the development process for the Green Chemistry regulations, DTSC has included an exemption, first as a *de minimis* exemption, then as an Alternatives Analysis Threshold, for substances that are present in products at very low levels. However, the revised proposed regulations replace these approaches with a proposal to establish a “Practical Quantitation Limit” (PQL) for each substance. This term is defined in Sec. 69501.2(a)(52) as “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.” In effect, this sets a “non-detectable” threshold as the threshold for conducting an Alternatives Analysis. Moreover, rather than apply to all substances, including intentionally added substances, the PQL exemption only applies to contaminants. The net result will be that companies will have to undertake the expense of an Alternatives Analysis for substances present in Priority Products as contaminants at detectable levels. For intentionally added chemicals, DTSC will consider an Alternatives Analysis Threshold only as part of the Priority Product listing process.

While FJATA appreciates DTSC’s efforts to set scientifically sound analytical detection limits to test for chemicals of concern, the PQL approach is absurd and unworkable as a cornerstone of this rule. It will be resource-intensive and administratively difficult to set

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(...continued)

Jewelry components can include clasps and closures, spring rings, chains of different weights and sizes, beads, charms, pendants and more.

chemical by chemical PQLs, a substantial undertaking that will not provide additional protection of human health. Moreover, the PQL will almost invariably be significantly lower than any threshold of concern, whether for unintentional contaminants or for intentionally added chemicals. The delayed establishment of an Alternatives Analysis Threshold for intentionally added substances will leave many products in limbo while the Priority Products listing process is completed.

From a resource standpoint, establishing a “non-detectable” threshold for each individual chemical of concern will involve considerable burdens. In many cases, the detection limit will be dependent on the analytical equipment available at a given laboratory, resulting in substantial variation across laboratories. At the same time, “non-detectable” limits constantly evolve as testing equipment and analytical methods become more sophisticated, and testing to lower and lower limits – often in the low parts per billion range – can be exceedingly costly. Most importantly, however, in the majority of cases, as noted above, the PQL is likely to be substantially lower than any reasonable *de minimis*, safe level of exposure. For DTSC to create a costly testing burden, in essence triggering the need for an Alternative Analysis when a Chemical of Concern is present only in *de minimis*, but detectable, levels that do not present any risk to human health or the environment, will prove extraordinarily burdensome.

With regard to intentionally added components, as with unintentional contaminants, the failure to set an upfront *de minimis* threshold will create confusion in the market. Most substances, to have a technical functional effect, must be added in more than trace amounts. Once the list of Candidate Chemicals is finalized, we expect that customers will begin working with their suppliers to determine whether any products are implicated because of the presence of Candidate Chemicals. Without a *de minimis* threshold, every single product that contains a Candidate Chemical, regardless of whether it is intentionally added or is a contaminant present at an extremely low level that would be considered safe from an environmental and health perspective, is potentially a Priority Product. It will be necessary to wait for DTSC to complete the Priority Product listing process and develop an Alternatives Analysis Threshold before any products with an intentionally added substance can be eliminated from the review process. This delayed and bifurcated process will leave many companies and products with an uncertain regulatory status, when instead DTSC could establish a *de minimis* threshold that could adequately protect public health while providing companies the ability to provide their customers with assurances regarding their products.

FJATA recommends that DTSC adopt the approach included in an earlier proposed draft of these regulations, namely, adopting a reporting threshold of 0.1% by weight as the trigger for reporting purposes. This threshold reflects the European Union’s REACH legislation and Section 313 of the Superfund Amendments and Reauthorization Act. This would simplify the reporting process considerably and help maintain consistency throughout the regulating and regulated community. For these reasons, FJATA urges DTSC to abandon the PQL approach and reestablish a general *de minimis* exemption applicable both to unintentional contaminants and to intentionally added substances. Failure to do so will result in a crushing and unworkable burden.

## II. Regulatory Non-Duplication

FJATA urges DTSC to take avoidance of duplication as a guiding principle in moving forward with regulations. Section 25257.1(c) of the California Health and Safety Code restricts DTSC from adopting regulations under the GCI that duplicate or conflict with existing or pending regulations of other agencies that are consistent with the purposes of the GCI.<sup>2</sup> The proposed regulations attempt to implement this requirement by providing an upfront applicability exemption, stating that the regulations do not apply to any consumer product that DTSC determines is regulated by other laws that provide equivalent or greater protections with respect to the same public health and environmental adverse impacts and exposure pathways that are addressed by the regulations. DTSC is required to make this determination during the course of evaluating whether a chemical-product combination will be listed as a Priority Product. DTSC has also included a “Harmonization” provision, which states, “Nothing in these regulations authorizes the Department to supersede the requirements of another California State or federal regulatory program.”

FJATA respectfully submits that any potential hazards associated with jewelry are already covered by a variety of federal and state laws. Any additional regulation under the Green Chemistry law would be unnecessary and duplicative. For example, children’s products, including children’s jewelry, are currently regulated by the U.S. Consumer Product Safety Commission (“CPSC”) under the Consumer Product Safety Improvement Act of 2008 (“CPSIA”) and other statutes administered by CPSC, including the Federal Hazardous Substances Act (FHSA). CPSIA establishes a comprehensive, preemptive scheme for regulation of certain chemicals, such as lead and phthalates.

With regard to children’s jewelry in particular, the CPSC has been closely involved with the development of an ASTM standard: ASTM F 2923-11, Standard Specification for Consumer Product Safety for Children’s Jewelry.<sup>3</sup> The standard addresses hazards associated with children’s jewelry, including: the potential for exposure to cadmium from mouthing or swallowing small metal jewelry components and other parts of children’s jewelry; exposure to certain other chemicals in paints and surface coatings; hazardous liquids; nickel sensitization; hazardous magnets; batteries; and strangulation. The CPSC is enforcing this standard.

Similarly, California already has in place laws to address heavy metals in children’s and adult jewelry, *e.g.*, California’s Metal-Containing Jewelry law.<sup>4</sup> This law regulates the levels of

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<sup>2</sup> Section 25257.1(c) states, “The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article.”

<sup>3</sup> As developed by ASTM International Subcommittee F15.24 on Children’s Jewelry.

<sup>4</sup> Health and Safety Code Sections 25214.1-25214.4.2.

lead and cadmium in children's jewelry and lead in adult jewelry through limits on heavy metals in the materials used to make jewelry and relevant tests and related requirements.

A combination of requirements are currently in place sufficient to protect consumers from potential risks associated with jewelry. Therefore, further regulation by DTSC under the Green Chemistry regulations would be unnecessary and duplicative, posing a significant added and unnecessary burden on manufacturers and sellers of jewelry in California.

### **III. Definition of Reliable Information**

FJATA respectfully submits that the trustworthiness of a reviewer for purposes of determining whether data or information is "reliable information" should be determined with reference solely to the credentials and qualifications of the reviewer or data submitter. The purpose of the Green Chemistry Initiative is to develop a comprehensive approach to chemicals policy, with the goal of creating a systematic, science-based process to evaluate Chemicals of Concern, and identify safer alternatives to ensure product safety, while avoiding duplicative requirements.<sup>5</sup> "Reliable information" is a cornerstone of certain science-based decision processes in the regulation. For example, reliable information is used to support: (1) additions to the Candidate Chemicals list (Sec. 69502.2(b)) (where "reliable information" regarding a structure/function relationship with other chemicals, or the potential or actual exposures to a chemical, are aspects of the listing); (2) the evaluation of adverse impacts caused or potentially caused by a Candidate Chemical, as part of the Priority Product listing process (Sec. 69503.3(a)(3)) (where a structure/function relationship with other chemicals is possible); and (3) as a review criterion for DTSC to evaluate the compliance of Alternative Analysis Reports and Work Plans (Sec. 69505.8(a)(4)).

In the proposed regulations, the definition of reliable information includes as a criterion "[t]he degree to which the information has been independently reviewed by *qualified disinterested parties*" (emphasis added). First, it is unclear how DTSC intends to determine whether a reviewer is "disinterested." While we understand that DTSC seeks to ensure the trustworthiness of the information and data used to support the regulatory decision processes, rather than using a term like "disinterested," the real goal is to assure that individuals with the requisite education and experience are involved. Trustworthiness should be based on the capability of providing a scientific critique of information. This should be determined with reference to a reviewer's credentials and adherence to the principles of the scientific method, not the source of the reviewer's paycheck or affiliation with an organization. Therefore, we submit that DTSC should remove "disinterested" from the definition of "reliable information," and simply require that reviews be conducted by "parties qualified by education and experience."

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<sup>5</sup> See Initial Statement of Reasons (ISOR), page 8.

#### **IV. Definition of Manufacturer**

The proposed regulations define a “manufacturer” to mean any person who manufactures a product, or any person that “controls the manufacturing process for, or has the capacity to specify the use of chemicals in, such product.” This definition has the potential to be very broadly applied and to perhaps create questions or conflicting compliance obligations. For example, if a retail customer includes specifications for the products it purchases with regard to the content of heavy metals, or relies on a testing laboratory or consulting firm to do so, this could potentially put the retail customers or laboratory in the position of a “manufacturer.” While we understand that DTSC’s goal is to ensure that there is a responsible entity for every Priority Product, DTSC should clarify whether establishment of specifications for listed chemicals means the specifying entity becomes a “manufacturer.”

Elsewhere in the proposed regulations DTSC has differentiated between the requirements for manufacturers versus retailers. For example, in Section 69501.2(a)(1)(A), the proposed regulations state that a retailer is required to comply with the requirements of the regulations *only if* the manufacturer or importer fails to comply. We believe that DTSC intended the regulatory burdens to fall primarily on manufacturers. By defining manufacturer to include an entity that has the capacity to specify the use of chemicals in a product, however, the regulations create the potential for confusion and duplication. To avoid any confusion DTSC should provide guidance on how the definition of a manufacturer relates to the language in Section 69501.2(a)(1)(A).

#### **V. Conclusion**

FJATA urges DTSC to reconsider moving forward with the proposed regulations and to incorporate specific changes recommended here. It is especially critical to adopt a *de minimis* threshold for both contaminants and intentionally added substances. The current version of the proposed regulations will offer limited, if any, benefits to public health as compared to the extraordinary burdens involved with compliance.

FJATA appreciates the opportunity to submit these comments.

Cordially yours,

Brent Cleaveland, Executive Director

cc: Sheila A. Millar

# Food Packaging Coalition

1667 K Street NW Suite 1000  
Washington, DC 20006-1620  
(202) 974-5200

February 28, 2013

## Via Electronic and Regular Mail

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

### **Re: Comments on the Revised Regulations for Safer Consumer Products**

Dear Ms. Von Burg:

The purpose of this letter is to provide comments to the California Department of Toxic Substances Control (DTSC) regarding the revised regulations for Safer Consumer Products (SCP) issued on January 29, 2013, to implement Article 14 of chapter 6.5 of division 20 of the California Health and Safety Code (hereinafter, “the Green Chemistry Initiative” or “GCI”). These comments are being submitted on behalf of the Food Packaging Coalition, a group of trade associations that represent the majority of food contact materials suppliers in the United States as well as trade associations that represent the food industry.<sup>1</sup> Members of this Coalition have a critical interest in the availability of safe and effective materials for packaging, holding, storing, transporting and serving food products. The comments provided herein reiterate the Coalition’s position that food contact materials and substances used as components of food contact materials should be excluded from the scope of GCI regulations. We hereby incorporate by reference comments from the Coalition’s submissions on the draft SCP regulations dated November 1, 2010, December 3, 2010, December 30, 2011, and October 11, 2012, and on the revised Initial Statement of Reasons dated January 22, 2013, copies of which are enclosed.

The Food Packaging Coalition (hereinafter, “the Coalition”) appreciates DTSC’s efforts to continue the open stakeholder process during the development of implementing regulations for the GCI, a process in which the Coalition has participated since 2009. The Coalition commends

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<sup>1</sup> Specifically, these comments are being submitted on behalf of the American Chemistry Council - Plastics Foodservice Packaging Group, American Forest & Paper Association, Can Manufacturers Institute, Flexible Packaging Association, Foodservice Packaging Institute, Grocery Manufacturers Association, North American Metal Packaging Alliance, Inc., Paperboard Packaging Council, Recycled Paperboard Technical Association, and SPI- The Plastics Industry Trade Association.

DTSC's responsiveness to concerns raised by Coalition partners with the previous draft of the SCP regulations, in particular by restricting the designation of "Chemical of Concern" to Candidate Chemicals that are the basis for listing of a product-chemical combination on the Priority Products list, by removing the requirement for Alternatives Analyses to be completed by certified assessors, by excluding from the definition of "manufacture" acts that meet the definition of "assemble," and by expanding the definition of "reliable information" to incorporate study design, level of rigor, independent review, corroboration and replication of the information.<sup>2</sup>

The Coalition remains concerned, however, with DTSC's failure to address our request made repeatedly in comments for clear language excluding from the proposed SCP regulations food contact materials, which are already subject to a comprehensive federal regulatory program that ensures their safety for the public health and environment. In all of the Coalition's previous submissions enclosed with this letter, we have stated our position and provided information to support the fact that food contact materials are already fully and effectively regulated throughout the life cycle by the U.S. Food and Drug Administration (FDA) and California governmental agencies to protect public health and the environment. Our analysis demonstrates that further regulation of these materials by DTSC under the GCI would be duplicative and in direct conflict with the existing federal regulatory scheme.<sup>3</sup>

Food packaging and other food contact materials are essential to ensure the safety and quality of food. Modern packaging is designed to be inert and not transfer its components or have an effect on food. It is also carefully designed to preserve the quality of the food, prevent nutrient and flavor scalping, and extend the shelf life of products, preventing food waste. The inclusion of food contact materials within the scope of California's GCI will not further the goals of the green chemistry statutes and may actually impede our industry's development of new food packaging materials that can improve the safety and environmental profile of these materials, as well as the safety, quality, and availability of the food supply while reducing food waste due to spoilage.

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<sup>2</sup> Notwithstanding the improvements to the "reliable information" definition, the Coalition respectfully submits that DTSC should remove "disinterested" from the criteria of a peer reviewer's independence and trustworthiness, and simply look to the education and experience of the reviewer.

<sup>3</sup> CA Health and Safety Code Section 25257.1(c) states, "The department shall not duplicate or adopt conflicting regulations for product categories already regulated or subject to pending regulation consistent with the purposes of this article."

The Coalition also is concerned that DTSC has adopted a new “Practical Quantitation Limit” (PQL)<sup>4</sup> approach, rather than utilizing a standard *de minimis* threshold for when an Alternatives Analysis is required for both intentionally added components and unintentional contaminants. The Coalition has commented on prior versions of the PQL, namely the *de minimis* exemption and Alternatives Analysis Threshold. Now, however, DTSC has replaced these standardized approaches with the expensive, administratively difficult, and overly burdensome PQL approach. The PQL essentially establishes a threshold of “non-detectable” for analytically determining when an Alternatives Analysis is required. The PQL approach should be reconsidered because it is: (1) resource-intensive, as companies are forced to conduct testing in the low parts per billion or parts per trillion range; (2) administratively difficult, if not impossible within a reasonable timeframe, as DTSC will have to undertake significant scientific research to establish a PQL for each substance; and (3) overly burdensome without providing additional protection of human health, because for food packaging materials the PQL is likely to be substantially lower than any safe level of exposure. DTSC should consider a more pragmatic and viable approach for establishing a *de minimis* threshold for intentionally added substances, as well as unintentional contaminants.

Finally, the Coalition also believes that the SCP regulations fail to adequately protect trade secret and confidential business information. Section 69509(g) provides that a responsible entity preparing an Alternatives Analysis (AA) can only claim as trade secret a replacement chemical being considered as part of the AA, if the chemical is the subject of a patent application. This provision conflates trade secrets with patent protection, which are two distinct forms of intellectual property protection. DTSC has no legal basis to require entities to waive their property rights in their trade secrets, or to force entities to file for patent protection. Ultimately, the proposed “masking” provisions would place companies in the position of having to disclose their highly valuable trade secret product formulations, which would have a substantial adverse economic impact. Therefore, the Coalition strongly urges DTSC to provide more stringent protections for trade secret information.

For the reasons set forth above and in comments previously submitted by the Coalition, we respectfully request that DTSC exclude food contact materials and substances used as components of food contact materials from the scope of any regulations promulgated to implement the GCI, and also reconsider its approach to establishing a *de minimis* threshold and protecting trade secret information.

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<sup>4</sup> Defined in Sec. 69501.2(a)(52) as “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.”

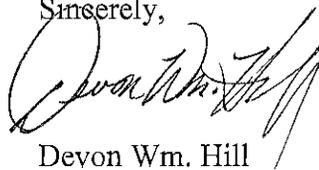
Ms. Krysia Von Burg

February 28, 2013

Page 4

We thank you for your efforts and consideration of our views and look forward to further collaboration as this process moves forward.

Sincerely,

A handwritten signature in black ink, appearing to read "Devon Wm. Hill". The signature is fluid and cursive, with a large initial "D" and a long, sweeping tail.

Devon Wm. Hill

Enclosures

February 25, 2013

Regulatory Staff  
Department of Toxic Substances Control  
California Environmental Protection Agency  
1001 I Street  
Sacramento, CA 95814

Colleagues,

I have reviewed the latest draft of the Safer Consumer Products Regulations (Department Reference Number: R-2011-02). This draft, like the previous draft, reveals the significant amount of work contributed by the Department in responding to the many comments put forward by the multiple stakeholders in this process.

Unfortunately, the years of adjusting and adding to the regulatory language to meet hundreds of specific concerns raised by the stakeholders has resulted in a text that is now burdened by a huge number of specified details and procedural requirements. This complexity is largely the consequence of trying to please many commentators with very specific concerns. I applaud the Department in preserving the fundamental structure and logic of the regulations, even as it needed to address these many comments.

However, the regulations would be improved by any efforts to shorten or streamline the required procedures, particularly the alternatives analysis process. I do see the value of a two stage alternatives analysis process, but I would encourage simplifying the first (preliminary) stage. It appears that there is duplication between the two stages, each requiring several similar steps. To simplify this, the first stage could focus more directly on the factors that are relevant to screening for acceptable, safer alternatives. The five step process should be preserved, but given less specification. The second stage could then focus more on the broader life-cycle issues that are called out in the statute. Of course, there could be draft reports or interim reports, but these need not be so carefully detailed. If the final report requirements are clearly specified, then drafts could simply be incomplete reports.

Rather than have separate Chemical Removal Intent/Confirmation, Product Removal Intent/Confirmation, Chemical/Product Replacement/Confirmation notifications; there could be one generic Petition for Exemption that permits several justifications. Similarly, instead of an Abridged AA and an Alternative Process AA Work Plan, there might be one generic Petition for Process Variance with several justifications (e.g. "no appropriate alternative discovered", "an alternative AA method preferred", "a previously completed AA exists"). Given that each of these (and other exemptions) is going to need a specifically tailored DTSC response, it would be more effective to maintain a one petition/one process review.

The Alternatives Analysis Threshold Notification procedure for chemical contaminants seems unnecessary. With sensitive enough detection equipment, unintentionally added contaminants should be discoverable in any product. Those contaminations readily identified should be reported as part of any good AA process. It does not appear necessary to make this a separate process.

My biggest concern involves the decision to abandon the private assessor. I have long argued that mobilizing the market to do more of the work in achieving the goals of the Safer Consumer Products Regulation made sense given the limited state budget. Others have argued that managing a state certified assessor program would be expensive, however, given the prospect of enlisting a host of talented

professionals in completing and/or evaluating the AA's, I argue that the up-front management costs would be more than offset.

However there are other benefits of the private assessor. The current regulation gives the DTSC a very truncated time to review AAs (60 days). Either this will result in an enormous backlog of missed deadline reviews or the reviews are going to be no more than compliance checks that do nothing to evaluate AA quality. Posting the AAs on the Internet will offer some opportunity for public review, but only in a very ad hoc and inconsistent manner.

Worse, by eliminating the assessor and the assessor certification process, the heart of the AA review process becomes a narrow, private dialogue between an AA preparer and an overworked DTSC staff person who will not have time to learn the technical details of the AA, offer comments that might improve the AA or improve the broader professional capacity for shifting products to safer alternatives. By creating a licensed pool of private professionals who engage AA preparers with technical insight and a desire to expand client relations, the AA review process builds a broad range of professionals throughout the private market who can be cross trained in technical and regulatory issues and who can, themselves, offer training and new technical assistance and consulting services for shifting to safer consumer products.

Were the preparation of these assessors and their evaluation the responsibility of the colleges or universities, this could create a new focus in the state higher education system for training professionals in safer chemistries and, in addition, develop curricula for training students in green chemistry and safer product design. You get all of this, simply by requiring that AAs be certified by licensed assessors and, in addition, you reduce the burden on DTSC staff.

I hope that these comments are helpful. I further hope that we are moving towards completion of the regulatory drafting process. California deserves to move on in implementing this law. Much will be learned in implementation and those lessons will be important for all of us who seek a shift towards safer chemicals and products.

Respectfully,



Ken Geiser, Ph.D.  
Professor Emeritus  
University of Massachusetts Lowell

Review  
Safer Consumer Products  
January, 2013 Revised Proposed Regulation

George M. Gray, Ph.D.  
Professor, Department of Environmental and Occupational Health  
Director, Center for Risk Science and Public Health  
George Washington University  
School of Public Health and Health Services  
Washington, DC  
March 4, 2013

I appreciate the opportunity to review the January 2013 Revised Safer Consumer Products Proposed Regulations. This iteration reflects continued thought and advice as the Department of Toxic Substances Control works to implement the requirements of Health and Safety Code section 25252.

My review is based on my understanding, developed through reading the materials supplied. My views come from my background as a risk analyst and toxicologist with a public health perspective. This review reflects my opinions and not necessarily those of George Washington University. I hope these comments will be considered along with my two previous sets of comments.

I begin with a few general comments about the revised regulations and then address the charge questions that were addressed to the peer reviewers.

My primary concern with the way the proposed regulations are structured is the very wide net that is cast in the beginning (the construction of the Candidate Chemicals list and the priority setting process) and the very narrow process of identifying priority products and conducting alternatives analyses (AAs). It is clear that the myriad of lists along with other criteria for identifying Candidate Chemicals will result in an initial list of hundreds or thousands of chemicals. Public concerns, and expectations, will be heightened when the presence of this large number of

potential chemicals of concern is identified. Yet the priority setting and listing process will begin with only five priority products. It seems to me that the potential for citizen frustration and dissatisfaction with the process will be very high.

In my view, a more targeted and risk-based approach to identifying candidate chemicals, which would result in a much smaller list, would be a more logical step. As I have noted in previous reviews, a list of candidate chemicals that is too long risks diluting effort, attention and resources. In addition, the presumably large Candidate Chemical list, based on many other lists, will doubtless cover the chemicals for which we have the greatest toxicological information. This will necessarily encourage the identification of new or less well-studied chemicals as potential alternatives in products or processes. Without a means to develop proxy hazard and dose-response information for these compounds we risk starting onto a “risk treadmill,” moving from chemical to chemical as new information becomes available. The tools of structural or mechanistic similarity referred to in § 69503.3 would be useful in this situation.

The AA sections seem more reasoned and reflects the challenge of doing AA well. The idea of “potential” effects or exposures is dropped and replaced with “a material contribution to one or more adverse public health impacts” for example. In addition, the multi-criteria nature of AA decisions, with different possible outcomes to different populations is recognized. I would hope that guidance and examples for AA would include some of the very good work ongoing to demonstrate tools for these difficult decisions<sup>1</sup>. I am especially struck by the recognition of the importance of quantitative analysis tools, weighing and comparing multiple attributes and optimizing decisions in contrast to the very simplistic hazard-based approach taken in developing the Candidate Chemicals list.

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<sup>1</sup> I., Sinsheimer P, Malloy T. Integrating Safer Alternatives into Chemical Policy: Regulatory Framework for AB 1879. Los Angeles, CA: UCLA Law and Environmental Health Sustainable Technology & Policy Program; 2009 pages 1–13; Malloy T, Sinsheimer P, Blake A, Linkov I. Developing Regulatory Alternatives Analysis Methodologies for the California Green Chemistry Initiative. Los Angeles, CA: UCLA Sustainable Technology and Policy Program; 2011 pages 1–65.

## Charge to Reviewers

The California statute for external scientific peer review (Health and Safety Code section 57004) states that the reviewer's responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following topics that constitutes the scientific basis of the proposed regulatory action. An explanatory statement is provided for the topic to focus the review. Section [25252-25257.1 of the Health and Safety Code](#) provide the authority and basis for developing the proposed regulatory text that is the focus of this peer review.

### Topics:

#### **1. The initial Candidate Chemicals are chemicals listed by one or more of the sources named in the regulations and have hazard traits that have public health and environmental concerns.**

*The broad list of chemicals is now called the "Candidate Chemicals" list. The regulations define "Candidate Chemical" as a chemical that is a candidate for designation as a "Chemical of Concern" (COC). A "Candidate Chemical" that is the basis for a product-chemical combination being listed as a Priority Product is designated as a "Chemical of Concern" with respect to that product. NOTE: For virtually all practical purposes, this change in terminology does not affect the duties of responsible entities subject to the regulations.*

*Revised regulations include the following two additional lists from authoritative organizations to the list of lists for the initial Candidate Chemicals list:*

- 1. Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.*
- 2. Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals in addition to the section 303(c) chemicals.*

*These lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically*

As mentioned above, the hazard-based approach to list development is likely to lead to an unwieldy, unfocused and difficult to manage set of Candidate Chemicals

The focus on existing lists does not address the seeming contradiction of using certain hazard traits to develop the list while not acknowledging that many chemicals may not have been tested for the trait. This is a shortcoming that that I identified in a previous review:

*“I am uncomfortable with the strong focus on specific hazard traits in both identifying COCs and in making de minimis determinations for two reasons. First, it is a well-established toxicologic fact that chemicals may have many different adverse effects. These effects may occur at different doses or be found in different test systems or species. Giving special consideration to carcinogens or compounds with “a reference dose or reference concentration has been developed based on neurotoxicity” in the EPA IRIS program, for example, misleads the public and, potentially, those conducting alternative assessments, about the specificity and accuracy of toxicologic values. For example, Xylenes; CASRN 1330-20-7, Toluene; CASRN 108-88-3 and 1,1,1-Trichloroethane all have oral RfD values in the IRIS database based on toxicologic outcomes other than neurotoxicity. Presumably, they would not be identified as having neurotoxicity as a hazard trait. But all three have positive results in toxicologic tests for neurotoxicity at some level of exposure.*

*The second concern arises because of the unevenness of the database for many compounds. For example, in IRIS, Acetone (CASRN 67-64-1) has an oral RfD based on nephropathy yet the IRIS file points out “the database lacks chronic, developmental, developmental neurotoxicity, and multigenerational studies and adequate neurotoxicity studies.” Here a compound can’t even demonstrate one of the hazard traits of concern because it has not been tested. Even if we had complete data we know that the concordance of hazard traits between test species and humans is not very good, even for chemicals used at pharmaceutically active doses in humans<sup>2</sup>.*

*The potency and levels of human or environmental exposure would be a more focused means of identifying CoCs.*

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<sup>2</sup> Olson, H., et al. (2000) Concordance of the toxicity of pharmaceuticals in humans and in animals. *Regulatory Toxicology and Pharmacology* **32**(1):56-67

I continue to be concerned about the fundamental structure of the Candidate Chemical list. A list built from lists of chemicals with existing toxicologic or policy concerns will fundamentally encourage the use of new and less tested materials. If the AA process is robust enough, this may not be a problem. Making the AA process sufficiently robust will be a challenge.

**2. Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.**

*The language for the key prioritization criteria have been clarified to illustrate that they must be met for proposing any Priority Product. Also, the phrase “ability to”, as in “The Chemical(s) of Concern in the product have a significant ability to contribute to or cause adverse public health and environmental impacts” has been replaced with “potential”: “There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product.” The revised proposed regulations define “potential” to mean that the phenomenon described is reasonably foreseeable based on reliable information.*

*The revised proposed regulations require the Department to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.*

Given the enormous number of chemicals likely to be on the Candidate Chemical list, the priority setting process must be rigorous and science-based to identify the right chemicals for further scrutiny. I have no confidence that the process in the revised proposed regulations will accomplish this. In my view, the change of the criterion from “ability to” to “potential” decreases the precision with which priority products can be identified. The change makes interpretation difficult (what does it mean to have “potential exposures which must contribute to or cause significant or widespread adverse impacts”?) and increases the possibility of arbitrary judgments about what evidence constitutes “potential” in both adverse effects and exposure contexts.

I would urge a return to the “ability to” language and, further, encourage development of guidance to clearly define how these judgments will be made. Some notion of causation along with criteria for evaluating both causation and attribution will be necessary.

I do not believe the use of biomonitoring data to as a prioritization factor can be scientifically supported (Section 69501.1 (a)(58)(B). Because biomonitoring data cannot apportion exposure to different sources and many Candidate Chemicals will have many sources of exposure (see Table) the identification of a chemical in biomonitoring studies does not indicate a product is a source of exposure.

Chemical	Candidate Chemical Hazard List	Non-Product Sources
Acetaldehyde	Proposition 65 Carcinogen	Fruits Coffee Cigarette smoke
Benzene	Proposition 65 Carcinogen and Reproductive Toxicant	Eggs Bananas Cigarette smoke Gasoline

**3. The principles outlined in the proposed regulations that establish the Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical**

*In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not be an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California’s Administrative Procedure Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an*

*alternative analysis threshold for a product-chemical combination should the need arise.*

The new approach to an Alternatives Analysis Threshold makes little sense to me. First, contrary to other regulations like those implementing Proposition 65, it is focused only on detection and has no role for the relative toxicity of a compound. In my view, an NSL-like approach, identifying a significant risk threshold, would be more scientifically sound. Second, it will be very difficult to administer. Constant advances in analytical chemistry mean the PQL will be a shifting target. The need to reexamine and update (and potentially revoke) threshold status will be constant, diverting effort and resources.

**4. The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.**

It is understandable and appropriate that the revised proposed regulations seek to identify and prioritize chemical uses that cause adverse effects on people or the environment. However, as defined in the 2013 Revised Proposed Regulations the term “adverse” is a confusing mix of qualitative, quantitative and theoretical effects with no concrete standard that must be met. For example, it is completely unclear who makes the designation, and which methods will be used, to identify “cumulative effects,” “aggregate effects” or “potential to contribute to or cause adverse impacts” under § 69503.3. As noted above, the use of the term “potential” exacerbates this problem because the word has no generally agreed upon scientific meaning.

In my view the use of loose language in defining “adverse” will lead to either very little prioritization (because every product-chemical combination will have the “potential” for some exposure or adverse effect) or accusations of arbitrary behavior in prioritization because some assertions of “potential” put forward will be accepted and some will not.

Additional comment: § 69503.2 – How will DTSC know there is a “readily available safer alternative....”? This seems to open the potential for lobbying and strategic behavior on the part of competitors or vendors.



# Green Chemistry Alliance

*Committed to Product Sustainability in the Global Economy*

Alliance of Automobile  
Manufacturers

February 28, 2013

American Chemistry Council

American Cleaning Institute

American Forest & Paper  
Association

California Chamber  
of Commerce

California League of Food  
Processors

California Manufacturers  
& Technology Association

California Paint Council

California Restaurant  
Association

California Retailers  
Association

Can Manufacturers Institute

Chemical Industry Council of  
California

Citizens for Fire Safety  
Institute

Consumer Healthcare  
Products Association

Consumer Specialty Products  
Association

Grocery Manufacturers  
Association

Independent Lubricant  
Manufacturers Association

Industrial Environmental  
Association

Metal Finishing Associations  
of Northern and Southern CA

National Paint and Coatings  
Association

Natural Products Association

Personal Care Products  
Council

Plumbing Manufacturers  
International

TechAmerica

Toy Industry Association

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

**Re: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (January 2013)**

Dear Ms. Von Burg:

On behalf of the Green Chemistry Alliance (GCA) and its coalition members, we respectfully submit the following comments relative to the Department of Toxic Substances Control's ("Department" or "DTSC") revised proposed Safer Consumer Products Regulation ("regulation") of January 2013. Additionally, GCA has filed comments to all prior iterations of the regulations, including the July 2012 proposal, all of which we incorporate herein by reference (See Appendix II).

GCA is a highly diverse coalition comprised of national and state trade associations and numerous large and small companies spanning the consumer market and global supply chain. Over the last four years and nine iterations of the regulations, GCA and its coalition members have largely coalesced around major aspects of the process and continuously offered productive solutions to aid the smooth implementation of the regulation. However, at the request of our coalition members, we are deferring to them to provide a more detailed critique of the regulation and offer sector-specific solutions to address their individual concerns. DTSC must be mindful of the unique issues these industries have identified in complying with the proposed regulatory program.

The business community has supported the goal of California's Green Chemistry Initiative to significantly reduce adverse impact to human health and the environment and many of our GCA founding members actively supported the 2008 enacting legislation. These members supported the legislation based on assurances that the framework would be anchored in strong science-based hazard and exposure evaluations and priority setting; that innovation would thrive; and trade secrets would be adequately protected. While we remain committed to the goals of the legislation, we remain **highly concerned that these high standards of scientific scrutiny and protection of intellectual property have not been met in this latest iteration.**

GCA appreciates the extensive effort DTSC has once again invested in its latest effort to develop a regulatory system that attempts to fulfill the Director's stated objective of being meaningful, practical, and legally defensible. **We acknowledge that changes we deem as improvements are embodied in the subject revised proposed regulation.** Some of the more significant improvements include:

- Adding language that explicitly states nothing in the regulation authorizes DTSC to supersede the requirements of any other California, state or federal regulatory program;
- Identifying the initial list of roughly 1,200 chemicals derived from 23 lists as "Candidate Chemicals" instead of "Chemicals of Concern." This is a positive change that incorporates feedback from the regulated community, taking into account the use, nature and extent of the exposure(s) in identifying human health or environmental safety concerns;
- Retaining a more focused subset of 230 Candidate Chemicals for the outset of the program through 2016; said chemicals to be selected on the basis of the chemicals' hazard traits AND exposure characteristics
- Retaining a focused startup for the program by selecting a maximum of 5 Priority Products (PP) containing a designated Chemical(s) of Concern (CoC);
- Requiring future updates to the PP list to be established and updated under the requirements of the Administrative Procedures Act (APA);
- Requiring companies to conduct the Alternatives Analysis, focusing on the CoC and potential replacement chemicals;
- Focusing on a product-chemical combination as the PP, thereby decreasing the likelihood of a regulatory treadmill for a product that no longer contains the designated CoC;
- Limiting the requirement to submit a revised Alternatives Analysis Report to only those cases where a selection decision changes and only within three years of DTSC approving a final Alternatives Analysis Report;
- Limiting the basis for, and application of, regulatory responses to the CoCs in any PP and any replacement chemicals on the Candidate Chemicals list; and
- Removal of concept of certified assessors and accreditation bodies.

While these provisions are largely seen by GCA members as positive and responsive to industry concerns and comments, when viewed as a package where each piece builds upon another, **the positive ramifications are often voided or offset by more onerous provisions.**

For instance, **the single most important provision to ensuring a workable program is establishing a concentration minimum for chemicals that would trigger the Alternative Analysis. GCA urges the Department to revise its latest approach on the use of the Practical Quantitation Limit (PQL) as the threshold for an Alternatives Analysis exemption.** DTSC decision to utilize the PQL as a threshold value effectively eliminates the concept of *de minimis* as a consideration, despite including reference to "intentionally added" and "contaminant," resulting in an unworkable regulation for businesses.

GCA and its coalition members have presented *de minimis* language on multiple occasions, and variations thereof, that would establish a default level consistent with other national and international regulatory jurisdictions while still allowing DTSC discretion to set a lower or higher *de minimis* value on a case specific basis as scientific information warrants.

As explained in the attached, the PQL is a laboratory quality procedure and does not have any health context. GCA urges DTSC to revise the proposed rule to enable manufacturers to demonstrate the safety of specific product/chemical combinations, as necessary. DTSC should not presume that the mere presence of one or more CoCs is reason to suggest potential harm. If manufacturers can demonstrate the safety of their product, the product should not be required to complete the AA process or have subsequent regulatory responses imposed. See attached detail for more information regarding the inappropriate use of the PQL as a threshold value.

In addition to the Alternative Analysis Threshold issue and its intended use of the PQL, GCA wishes to reiterate many of the serious concerns that we've raised time and time again which we continue to believe will keep the SCP program from being implemented as a deliberate science-based effort that focuses on actual public health and environmental safety associated with commonly thought of consumer products as was intended by AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). GCA members are highly concerned that the revised proposed regulatory framework:

- Fails to include an opportunity for a manufacturer to demonstrate the safety of a priority product through an analysis of, exposure to, and/or inaccessibility of the chemical from product use and disposal;
- Continues to suggest that DTSC has enormous discretion to determine whether a product-chemical combination should be subject to the regulation despite a specific statutory prohibition against superseding the authority of other state and federal regulations;
- Eliminates an upfront exemption for products in the supply chain of statutorily exempted products, particularly since DTSC does not have the authority to regulate the supply chain of exempted products and such action would be considered superseding the authority of another agency;
- Changes the word ~~impacts~~ to ~~effects~~ effectively subordinating the question of adverse impacts to hazard considerations alone. The language of the enabling statute is quite clear on this issue and chooses the word ~~impacts~~ on eleven (11) occasions. As NGOs have argued for the restoration of the word ~~potential~~ over the word ~~ability~~, GCA calls upon DTSC to restore the use of the word ~~impacts~~.
- Continues to permit unknown parties to submit unlimited and vexatious petitions implicating otherwise unremarkable products. Article 4 contains no meaningful limitations on the number, scientific validity or frequency of petitions."
- Continues to provide only a ~~narrative~~ product-chemical prioritization process that could lead to examination of product-chemical combinations that will provide little or no meaningful improvement in public health and the environment;
- Fails to adequately protect trade secrets, such as chemical identities, and presumes that patents are sufficient to protect a company's intellectual property;
- Requires manufacturers to provide a listing of all retail sales outlets in the Alternatives Assessment reports, which is clearly proprietary information that goes beyond DTSC's statutory authority.
- Provides inadequate timelines, fails to adequately consider consumer acceptance, has limited economic feasibility criteria and requires an external economic impact analysis for conducting alternatives analyses;

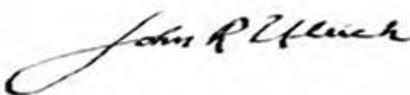
- Provides for a public comment process on all Final AA Reports, particularly with this being a regulatory program whereby the review should be the responsibility of DTSC;
- Will be impractical and unworkable, in many situations bordering on arbitrary decision making, will stifling innovation, and will create a compliance liability issue for Responsible Entities;
- Will impose unnecessary costs and administrative requirements on companies that result in higher priced products for California consumers;

These concerns, while not exhaustive, not only question the practicality, meaning, and legality of the regulation, but also raise issues regarding the necessity, clarity, and consistency of various components of the regulation.

The Department has opted to focus the program initially by identifying up to five Priority Products. While this is a practical approach that will enable the Department to conduct an orderly startup, learn what works and does not work, and make adjustments accordingly, it is not a panacea. Identification and prioritization of a single product-chemical combination could result in a multitude of individual brands as well as domestic and non-domestic manufacturers being responsive to the regulation. As suggested by the EU Commission on one of the previous versions of the proposed regulation, a pilot phase could accomplish the goals of testing out this unique and complex program without creating compliance liabilities for the regulated community. When GCA members consider how the proposed regulations might be implemented, one issue that is most perplexing is that virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products. This will certainly lead to arbitrary selections and decisions based on qualitative rather than quantitative information. As a consequence 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.

GCA and its coalition members strongly support the noted improvements, but continue to have serious concerns with the proposed regulation as revised. We appreciate your consideration of our concerns. For further information or questions regarding the Green Chemistry Alliance, its members, or the attached comments contact John Ulrich (916) 989-9692 or Dawn Koepke (916) 930-1993. You may also visit the GCA website at [www.greenchemistryalliance.org](http://www.greenchemistryalliance.org). Thank you!

Sincerely,



John Ulrich  
Co-Chair  
Chemical Industry Council of California



Dawn Koepke  
Co-Chair  
McHugh, Koepke & Associates

*Attachment*

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

## Appendix I

### Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (January 2013)

#### Green Chemistry Alliance Key Issues of Concern

In response to the subject revised proposed regulation The Green Chemistry Alliance (GCA) offers the following comments and suggestions concerning specific sections. Importantly, the following is but a focused set of issues and does not necessarily cover the full spectrum of concerns held by industry. As previously noted, GCA defers to the various trade associations and individual companies to provide more thorough evaluations based on their individual positions and perspectives.

- **§ 69501 – Purpose and Applicability**

In 3(A), as currently written, DTSC could regulate a product already regulated by another state or federal agency by simply asserting that by listing the product as a Priority Product the protection afforded the public would be greater than that which is afforded by the regulations of the other agency. To adequately prevent regulatory duplication as required by the underlying statute (Health and Safety Code Section 25257.1(c)), we recommend **striking subsection 3(A) 1 and 2**. As written, the proposed Regulations provide an open door for unnecessary regulatory duplication or adoption of conflicting regulation. The very fact that an agency of state or federal government and/or applicable treaties or international agreements having primary jurisdiction for regulating certain public health or environmental activities elects not to regulate said activity exactly as DTSC might choose to regulate should not give DTSC license to intervene.

- **§ 69501.1 Definitions**

**(8) “Adverse Waste and End-of-Life Effects”** – This definition is incorporated into the criteria for prioritizing chemical/product combinations to trigger Alternative Analysis (-AA”) or regulatory action. The use of these effect characteristics **are not appropriate criteria** for determining DTSC requirements for AA or regulatory responses. As provided for in the underlying statute, waste and end-of-life disposal are criteria required to be evaluated as part of the Alternative Assessment and **not** for prioritization. Health and Safety Code Section 25253(2)(j).

**(12) “Alternatives Analysis Threshold”** – *“Alternatives Analysis Threshold” means the Practical Quantitation Limit for a Chemical of Concern that is present in a Priority Product solely as a contaminant.* The Practical Quantification Limit (-PQL”) is a procedure to determine the quality / validity of an analytical laboratory measurement. **It is not appropriate to use PQL as an indicator of safety** as it is after all merely an analytical detection limit and NOT a measure of or even an indication of exposure that results in an adverse impact. Rather, it is in fact a policy decision of the most extreme case. PQL is an exceptionally low value, which effectively nullifies the concept of a *de minimis*, and its use as a threshold value is meaningless. An appropriate policy decision would be to set a numerical *de minimis* threshold that aligns with international standards (i.e. 0.1% by weight).

Further, as noted below the use of the PQL creates a lack of both clarity and certainty for the regulated community. There are several reasons why the PQL is an inappropriate value to be used to establish the Alternatives Analysis Threshold (AAT). **The PQL is a relative value that is dependent upon the analytical method and the material being**

**tested.** The DTSC should recognize the PQL for any given chemical of concern can vary based on the matrix in which the chemical is contained. This matrix can impact the degree to which the chemical can be detected as well as the appropriateness of any given analytical methodology to detect the chemical. Additionally, the PQL can and does carry a variety of definitions in practical application. As examples, the term “PQL” is defined in several ways by various governmental agencies.

- The lowest level that can be reliably achieved during routine laboratory operating conditions. The PQL is approximately two to five times the calculated MDL (Method Detection Limit). (Vermont Department of Environmental Conservation)
- The lowest concentration where the 95% confidence interval is within 20% of the true concentration of the sample. The percent uncertainty at the 95% confidence level shall not exceed 20% of the results for concentration greater than the PQL. (United States Department of Energy)
- Practical Quantification Limit (PQL) means the minimum concentration of an analyte (substance) that can be measured with a high degree of confidence that the analyte is present at or above that concentration. (Colorado Department of Public Health and the Environment)

Supporting data for compliance with this regulation may be submitted from laboratories across the US or around the world. The PQLs from each of these laboratories for the same chemical of concern could be different yet equally correct. As a result, different Responsible Entities may or may not claim a Threshold Exemption for the same Priority Product based on different PQLs. Most importantly, the PQL is an unnecessarily low threshold that essentially renders the AAT exemption ineffective. The use of such a low threshold could require Responsible Entities to devote significant resources to conduct Alternatives Analysis on chemical/product combinations with negligible quantities of a chemical of concern for which there is no reliable information to indicate the chemical poses any risk at that level.

DTSC’s revised proposal fully eliminates the concept of *de minimis* as a consideration, making the regulation completely unworkable for businesses. While the incorporation of the terms “intentionally added” and “contaminant” are welcomed, there is absolutely no practical benefit from the inclusion. Contaminants must be below the Practical Quantification Limit (PQL) - in essence if the presence of something can be measured with confidence, it no longer benefits from the exemption and is subject to an AA. **With no practical safe harbor level the proposal is unscientific and inconsistent with standards set elsewhere in federal and international chemical control systems. It provides no certainty for responsible entities to comply with the regulation.**

**DTSC should remove the PQL as the threshold value and create a clearly defined, science-based *de minimis* threshold value for each chemical/product combination. The creation of this *de minimis* value would improve the clarity of the regulation and enhance compliance efforts.**

An effective *de minimis* threshold value established for each chemical/product combination, as previously recommended would address this problem. Recall, GCA and its coalition members have presented language on multiple occasions, and variations thereof, that would establish a default level consistent with other national and international regulatory jurisdictions while still allowing DTSC the discretion to set a lower or higher *de minimis* value on a case specific basis as scientific information warrants.

DTSC's proposed regulation should not presume that the mere presence of an identified CoC is reason to suggest potential harm. If manufacturers can demonstrate the safety of their product, the product should not be required to undergo the AA process. **DTSC should provide an opportunity for manufacturers to present data supporting and alternative threshold level for contaminants and ingredients and to prepare a "safety case" demonstrating the safety of a product/COC combination. GCA urges DTSC to revise the proposed rule to enable these demonstrations**

**Outright elimination or removal of CoCs in products is the proposed favored approach.** The PQL concept as drafted will force manufacturers to analyze each intentionally added CoC in the Priority Product, irrespective of the risk posed by the chemical(s) in the product. This does not meet the practical or meaningful standard the Director has set for the regulation. GCA is concerned that the Department is relying too heavily on chemical elimination rather than safe use and incremental improvement. This approach is contrary to the statutory requirement under AB 1879 (Feuer, 2008) that DTSC's regulations must "...determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern..." DTSC should recognize the importance and benefit of incremental improvements as this program commences. Based on a manufacturer's demonstration of safe use for particular chemicals in a particular product, limiting exposure or reducing the level of hazard posed should be sufficient for compliance.

**It is imperative for the workability of the program that this provision be further revised in line with recommendations provided by GCA. We urge the Department to revise their approach on this provision as the single most important provision to ensuring a workable program.**

**(29) "Economically feasible"** means that an alternative product or replacement chemical does not significantly reduce the manufacturer's operating margin. This definition calls upon DTSC to make a judgment concerning the sufficiency of a manufacturer's margin that is inappropriate for them to make. It also assumes that increased costs of alternatives can be built into pricing, which is absolutely not the case. Until a company knows the customer acceptance of a product thereby driving demand, the company does not know what their margin is and in a competitive landscape, this can be very dynamic. Other factors that impact variable cost will also affect margin. Margin also varies by market segment. It seems impossible for DTSC to have the knowledge to make the judgment or decisions in this area. **GCA recommends that this definition be changed to reflect a straight comparison of costs between the baseline and alternatives.**

**(52) "Practical Quantitation Limit" or "PQL"** means the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures. Please see comments above on (12) Alternatives Analysis Threshold.

- **§ 69503.2 Product-Chemical Identification and Prioritization Factors.**

(a) *Key Prioritization Principles.* Any product-chemical combination identified and listed as a Priority Product must meet both of the following criteria

(1) There must be **potential public** and/or aquatic, avian, or terrestrial animal or plant organism **exposure** to the Candidate Chemical(s) in the product; **AND**

(2) There must be the potential for one or more exposures to contribute to or cause **significant or widespread** adverse impacts.

GCA supports the use of the conjunctive "and" for identification and listing as a Priority Product.

In terms of concerns, numerous definitional changes have been made in the various “adverse impacts” definition to make those terms equivalent to “adverse effects”. “Adverse impact” as used in the statute and in OEHHA’s hazard traits, incorporates the concept of magnitude and extent of a hazard property. “Adverse effect” focuses solely on the particular hazard endpoint with no broader consideration. While every chemical has numerous measurable “effects”, only some have significant adverse impacts under certain conditions of exposure. **GCA recommends that all adverse impact definitions eliminate the term “effect”, replacing it with “impact” per the statutory basis.**

Additionally, the term “potential”, which had been largely dropped in the July 2012 proposal (e.g. potential adverse effects, potential exposures, etc.), has been added to virtually every definition, prioritization criterion and consideration. This could drive a loss of focus in the process and lead to being overwhelmed with all manner of hypothetical scenarios. This change is somewhat mitigated by the addition of a definition for potential – “...that the phenomenon described is reasonably foreseeable based on reliable information”. The Department needs to concentrate focus on expected and probable health and environmental concerns, not every imaginable possibility. **GCA recommends that the definition of the term “potential” include the concept of likelihood, e.g. “...that the phenomenon described is likely and reasonably foreseeable based on reliable information”.**

Further, in the updated narrative standard, § 69503.2 (b)(1)A, the Department is required to consider “...one or more of the factors listed in § 69503.3 (a) and one or more of the factors listed in § 69503.3 (b)...”. The references are to a variety of adverse impact and exposure factors. In addition, this “one or more” construction is utilized in the referenced section § 69503.3 for both (a) and (b). This statement is not logical – the Department should be required to consider all of those factors where there is available information, and not jump to conclusions based on just one factor. This does not require all information to be available, in fact the proposal specifically says “...for which information is readily available”. **GCA recommends that the term “one or more” be stricken from all of its uses in § 69503.2 (b)(1)A, § 69503.3 (a) and § 69503.3 (b) so that all factors for which there is readily available information would be considered in the identification and prioritization process.**

Also in the updated narrative standard, a vital phrase has been eliminated from the Key Principles that has been employed in every previous regulation draft. It establishes the demonstration of potential for exposure to the chemical in the product “in quantities that would contribute to or cause adverse...impacts”. This is a critically important part of the Principle and should be reinstated. The exposure factors in § 69503.3 (b) are very broad-based and all are relevant, however, the focus in the exposure criteria often seems to be on “presence”, “contact” and “occurrence”, which are not the same as exposure. This suggests an entirely qualitative evaluation, which could result in opinions and emotion driving the process, potentially resulting in arbitrary decisions rather than a deliberative scientific effort to identify high priorities—i.e., real and significant threats to public health and the environment. Qualitative information, while directionally helpful in indicating existence, occurrence, contact or presence, cannot be sole factors in determining whether a situation creates an exposure with the potential for adverse impacts. Presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern must be a primary driving factor in priority setting decisions. The one provision that previously mitigated this concern was in the previously “Key Prioritization Factors” (Now Key Principles”) area.

**GCA recommends that the underlined phrase be reinstated in the Principles, § 69503.2(a)(2) - “There is significant ability for public and/or aquatic, avian or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts”.**

(2) *Other Regulatory Programs.* This sub section provides the DTSC with authority to regulate a product already regulated as a Priority Product simply by claiming enhanced protection under the proposed regulation. This reservation of discretion to DTSC is not authorized by the underlying statute and goes beyond the delegated statutory authority specifically limited under Health and Safety Code Section 25257.1(a) -(c).

(3) *Safer Alternatives.* DTSC may use its judgment as to whether a safer alternative may exist as part of its criteria when prioritizing product-chemical combinations. Despite the long list of public health, safety and environmental concerns identified in the regulation as prioritization factors, this discretion afforded to DTSC allows for prioritization based on convenience. Protection of the public should be based upon the existence of actual hazard, together with routes of significant exposure for the hazard that can cause an adverse impact. Convenience is an inappropriate prioritization factor.

- **§ 69505.1. Alternatives Analysis: General Provisions.**

(2) Public Comment on each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan submitted to the Department. **Public comment on AA reports is inappropriate for a number of reasons.** It has been posited by DTSC that the reason for public comment is to provide “a quality assurance mechanism”. Quality assurance is provided by an employee of the Responsible Entity with the requisite skills and expertise to conduct an informed review of the assessment materials. As in other environmental regulations the regulatory agency is the “quality assurance” reviewer rather than the public or a third party. Public comment does not equate to quality assurance as the general public on a whole lacks this knowledge. Further, public comment cannot possibly be based on complete information, as most if not all AA reports will have significant amounts of redacted competitive Trade Secret information – economic, technical and functional – that will only be available to DTSC.

Public comments on the decision making process will only serve to delay and potentially misguide the alternative assessment process. The public has no expectation that it will be directly involved in the internal decision making process of a Responsible Entity's selection of an alternative for a Priority Product. The Responsible Entity is just that - *responsible for the work product*. The decisions and selections made are those of the Responsible Entity and unique to that entity. The decision making process should be based on a Responsible Entity's own internally identified criteria and not be affected or constrained by a public that does not fully understand its business concerns, legal liabilities and technology constraints. It is more appropriate for the public to provide their feedback for a Responsible Entity's choice in the marketplace through their buying preferences. It is unclear what level of response to comments will be needed and what liabilities may arise due to the decisions made and the response to such comments.

In addition, the **requirement that AA reports be made available for public comment creates serious and unnecessary competition-law concerns.** Specifically, because the AA reports are required to contain economic, technical and functional data, including a detailed review of the economic and technical feasibility and the functional acceptability of various considered alternatives, any public comment requirement essentially mandates

the opening-up of competitively sensitive information to the horizontal competitors of the Regulated Entity. Such sharing of competitively sensitive information creates potential exposure under the federal antitrust laws, and that exposure cannot be eliminated or minimized on the grounds that the information sharing is mandated by state law. In fact, the federal antitrust law on this topic is quite clear that potentially anticompetitive behavior cannot be shielded by state law from antitrust scrutiny unless the anticompetitive behavior is “clearly articulated and affirmatively expressed” by the state law. At the very least, the anticompetitive behavior must be a “foreseeable result” of what the state has authorized. In this case, the underlying legislation (AB 1879 and SB 509) cannot meet any of these tests. Indeed, the underlying legislation is focused on traditional environmental, health and safety (“EH&S”) purposes; there is no clearly expressed intent to displace commercial competition, and such displacement is not a foreseeable result of the EH&S goals expressed in the underlying legislation<sup>1</sup>. Health and Safety Code Section 25253(a)(1).

Because the Regulated Entity would remain exposed to potential federal antitrust liability for knowingly sharing commercially sensitive information with its competitors, the proposed regulation could only be permissible if such information sharing, which is generally contrary to federal competition law policy, were mandated by state law or at least a foreseeable result of state law. In this case, the underlying state law does not have a sufficiently expressed state policy in favor of information sharing by competitors, and such information sharing is not what one would reasonably foresee from a traditional EH&S statute.

- **§ 69505.3. Alternatives Analysis Threshold Notification in Lieu of Alternatives Analysis.**

The AA Threshold has been for all practical purposes stripped of all value to a Responsible Entity by defining the threshold as a moving target. Based on the definition, PQL is essentially the smallest amount of a chemical that can be reliably measured. As such, the end result is “if you can measure it, you must account for it”. By applying the threshold only to contaminants, the logical extension is that a Responsible Entity must account for an intentionally added Chemical of Concern, even if it cannot be reliably measured. The PQL makes the threshold irrelevant. Placing the AA Threshold at such a low level means Responsible Entities could spend significant resources to conduct AAs on products with negligibly measureable quantities of a substance for which there is no data to indicate the substance poses the potential of an adverse impact at that level

- **§ 69505.6. Alternatives Analysis: Second Stage**

*(a)(2)(C)1. Economic impacts. This section instructs Responsible entities to evaluate “a. Public health and environmental costs; and b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.”* To properly monetize these costs would be difficult at best for the most sophisticated Responsible Entity and next to impossible for all others. Further, this approach will result in a wide array of assessments, each one different even if on the same CoC and replacement chemical, thereby making the analysis irrelevant.

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<sup>1</sup> The Supreme Court has just recently reaffirmed all these federal antitrust law principles in the case of *Federal Trade Commission v. Phoebe Putney Health System, Inc.* (slip op. February 19, 2013) (holding that Georgia law creating local hospital authority did not express a state policy to displace competition through permitting potentially anticompetitive hospital mergers).

**DTSC must retain the responsibility to evaluate the economic impacts to the state** and to avoid doing so in this case attempts to shift the burden to the regulated community. Government Code Section 11346.3(b). The abdication of this responsibility is just another example of DTSC's unauthorized shifting of responsibility from the state to Responsible Entities. All that is accomplished by this exercise is an increased burden to manufacturers that will result in an inability on the part of the Responsible Entities to comply.

- **§69509. Assertion of a Claim of Trade Secret Protection**

As mentioned in the cover letter, GCA continues to be concerned that the proposed regulations diminish the existing trade secret protections provided in California under the Public Records Act.

GCA continues to adamantly oppose the provision eliminating protection for chemical identity in connection with the submission of hazard trait information. Not only is the approach outlined in the regulation unnecessary, it exceeds the department's authority under the statute. Hazard information is distinct from chemical identity. Importantly, Chemical identity should always be claimable as a trade secret. Traditionally, generic chemical names are provided in connection to the hazard information, which are sufficient for meeting statutory requirements and enabling an appropriate level of public information for the safe use of chemicals. From a policy standpoint, asking companies that have invested millions of dollars on the development of new technologies and products to make them public thus benefitting competitors makes no sense.

The updated proposal allows chemical identity to be claimed as a trade secret if a patent is pending. This shows little understanding of existing commercial practices. Chemical identity is rarely the subject of a patent. A patent is a process that discloses secrets regarding formulations and manufacturing processes. As such, the vast majority would not be patented, but rather would be protected as trade secrets.

While the inclusion of federal law and non-disclosure agreements as criteria for trade secret protection makes sense, these exceptions do not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade secret. **GCA recommends that the chemical identity always be claimable as a trade secret and that the phrase "...or for any chemical identity information associated with a hazard trait submission" be deleted from 69509(f).**

These concerns are heightened due to the changes made to the definition of Responsible Entity and addition of Assembler in the proposed regulations. These changes create a situation that may cause inadvertent disclosure of trade secrets or other proprietary information to DTSC in the numerous documents that are being requested of Responsible Entities. **GCA suggests that DTSC consider including the ability for the owner of a trade secret to provide the confidential information directly to DTSC.** This process would be similar to that adopted by the U.S. Environmental Protection Agency under the Toxic Substance and Control Act (TSCA) for Chemical Data Reporting (CDR) purposes for joint submission to protect confidential information. 40 CFR 711.15(b)(3)(i)(A)-(C).

GCA believes the proposed regulation amount to an unlawful taking by eliminating a Responsible Entity's ability to consider whether to file for patent protection or retain the information as a trade secret. The proposed regulation punishes Responsible Entities in that it forces a company to file for patent protection thus taking away the option to keep the information as a trade secret. Article 1, Section 19 of the California Constitution provides: "Private property may be taken or damaged for public use only when just compensation, ascertained by a jury unless waived, has first been paid to, or into court for, the owner."

To the same effect, the Just Compensation Clause of the Fifth Amendment of the U.S. Constitution states —. nor shall private property be taken for public use, without just compensation.” Most forms of intellectual property have been recognized and accepted by the Supreme Court as being ~~property~~” as protected under these provisions<sup>2</sup>. The Proposed regulations do not provide any compensation for the loss of the ability for a company to protect information as proprietary or trade secrets and therefore it is an unlawful taking by DTSC.

The lack of strong protections for trade secrets in the proposed regulations counteract the efforts of the President’s Administration as outlined in the recently released strategy which highlights the real threat of corporate espionage and how failure to protect intellectual property creates an enormous disadvantage to U.S. companies. The disadvantage comes from not being able to protect innovation, ingenuity and creativity in the global marketplace. DTSC’s revised proposed SCP regulation would ignore the strong messages in the Administration’s Strategy and provide an open door to all competitors to access sensitive information<sup>3</sup>.

- **Economic Analysis**

While the Department filed the Std. Form 399 last in the Fall of 2012, as required under the Administrative Procedures Act (APA), it is generally acknowledged, even by DTSC, that the Form filed was woefully inadequate and devoid of any substantive information. DTSC indicated the lack of economic analysis which throughout the document read as ~~unknown~~” should more properly have read ~~unknowable~~.”

DTSC subsequently indicated in press statements and letters to the legislature that upon adoption of the regulations it intended to conduct economic analyses consistent with SB 617 (Calderon, 2011) on designated Priority Product/CoC combinations. While we appreciate that the listing of future product-chemical combinations will be conducted in accordance with the Administrative Procedures Act (APA), which requires economic review, under the revised proposed regulation, we remain highly concerned that the first set of up to five product-chemical(s) combinations are not subject to any semblance of economic analysis. The Green Chemistry Alliance continues to be highly concerned that the recurring theme throughout the document was that the economic and fiscal impact of the proposed regulation will only be quantifiable after the regulation is implemented and operating.

GCA cannot help but observe that the issues we have noted in the above and in earlier comments filed over the past four years, regarding lack of focus, lack of exemptions, narrative prioritization processes, lack of quantification and standards, regulatory duplication, compromised trade secrets, and unfettered discretion are unstated underlying impediments preventing a quantifiable economic impact analysis of the regulation as proposed. We urge DTSC to carefully evaluate GCA proposals and recommendations and adopt same in order to facilitate a full and effective implementation of the enabling legislation

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<sup>2</sup> See, *Ruckelshaus v. Monsanto Co.* 467 U.S. 986 (1984) (the Court recognized that ~~a~~ trade secret property right is protected by the Taking Clause of the Fifth Amendment.” *Id.* at 1003-04), *Lane v. First Nat'l Bank*, 871 F.2d 166, 174 (1st Cir. 1989) (finding that copyright “taken for public use” gives rise to “a constitutional right to just compensation”); *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) quoting *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979)) (the Court recognized the protection of patents stating that the ~~all~~mark of a protected property interest is the right to exclude others. That is one of the most essential sticks in the bundle of rights that are commonly characterized as property.”)

<sup>3</sup> —Administration Strategy on Mitigating the Theft of U.S. Trade Secrets” (—Administration’s Strategy”). The Administration’s Strategy is available at: <http://www.whitehouse.gov/blog/2013/02/19/launch-administration-s-strategy-mitigate-theft-us-trade-secrets>.

## Appendix II

### Green Chemistry Alliance Comments Incorporated by Reference

**GCA comments on SCP regulation** Oct. 11, 2012

<http://greenchemistryalliance.org/Media/SCP%20Regulation%20GCA%20Ltr%20Final%2010-11-12%20copy.pdf>

**GCA comments on SCP informal draft** Jan. 13, 2012

<http://greenchemistryalliance.org/Media/GCA%20SCP%20Draft%20Reg%20Comment%20Ltr%20%201-13-12-Final.pdf>

**Comment letter on revisions to SCPA** Dec. 3, 2010

[http://greenchemistryalliance.org/Media/DTSC\\_SCPA\\_Revisions\\_GCAcomment\\_20101303.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1](http://greenchemistryalliance.org/Media/DTSC_SCPA_Revisions_GCAcomment_20101303.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1)

**Comment letter to DTSC** Nov. 1, 2010

[http://greenchemistryalliance.org/Media/GCA\\_Comments\\_re\\_EPC\\_Evaluation\\_of\\_proposed\\_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1](http://greenchemistryalliance.org/Media/GCA_Comments_re_EPC_Evaluation_of_proposed_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1)

**Comments to CEPC on need for EIR on regulations** October 26, 2010

[http://greenchemistryalliance.org/Media/GCA\\_Comments\\_re\\_EPC\\_Evaluation\\_of\\_proposed\\_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1](http://greenchemistryalliance.org/Media/GCA_Comments_re_EPC_Evaluation_of_proposed_SCPA%20Regs.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1)

**Comment letter to DTSC** July 22, 2010

<http://greenchemistryalliance.org/Media/GCA-Comment-Ltr7-22-10-Final.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1>

**Comments - Safer Alternatives Regulations** May 27, 2010

<http://greenchemistryalliance.org/Media/FinalGCAComments-SaferAlternativesRegs05.27.10.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1>

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February 28, 2013

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

**Re: Comments on Updated Proposed Regulations - Safer Consumer Product Alternatives**

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of consumer packaged goods through scientific excellence. The GMA Board of Directors is comprised of chief executive officers from the Association's member companies. The \$2.1 trillion consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

GMA appreciates the opportunity to submit the following comments in response to DTSC's January 2013 Post-Hearing Proposed Regulations for Safer Consumer Product Alternatives (updated proposal). We recognize the extensive DTSC staff efforts that have gone into these revisions. In particular, we appreciate and strongly support Director Raphael's direction to make the Safer Consumer Products regulation practical, meaningful and legally defensible. Applying and balancing these concepts can be a pathway to achieving the Green Chemistry Initiative's objectives.

GMA has filed substantial comments to all previous iterations of the regulations, including detailed comments on the July 2012 Proposed Regulations, which we incorporate here by reference. (For a copy of those comments, please see: <http://www.gmaonline.org/issues-policy/product-safety/chemicals-management/green-chemistry/state-comments/>).

The updated proposal makes and affirms a number of strategic choices that will help in creating a program to improve public health and the environment for all Californians:

- The update makes a shift in identifying the approximately 1200 chemicals that will end up being selected from 23 specific lists as "Candidate Chemicals" instead of "Chemicals of Concern". This is a positive change, as it is not possible to identify concerns for the human or environmental safety of a chemical without considering how it is used and the nature and extent of exposures in its lifecycle.
- The update continues to indicate an approach in which the Department will identify approximately 230 Candidate Chemicals for the initial focus in the program through 2016. GMA strongly supports the concept behind this approach, which uses information on chemical hazard together with indicators of exposure to narrow the field. This is a critically important step forward, highlighting a core group of substances to make progress on in the initial years of the program, while sending an important signal to the marketplace. GMA encourages DTSC to continue to use a similar approach, considering hazard and exposure for focus Candidate Chemicals beyond 2016.

- DTSC continues to indicate that in the first round it will select up to 5 Priority Product (PP) and associated Chemicals of Concern (CoC). GMA has advocated for and supports this approach to enable focused learning and building on success in the initial stages of implementation.
- The Update would also require the listing of Priority Products to be established and updated through APA rulemaking. This provides a more formal framework for these decisions, and is welcomed; however, this benefit is undermined by further relaxing the standards for Priority Product decision-making (addressed in more detail below).
- DTSC’s approach to the alternatives analysis (AA) process continues to expect companies to conduct the Alternative Analysis, reaching their own decisions on any product changes. It also preserves other improvements that were noted in GMA comments on the July proposal. In particular, the clarification in the update that an AA should be focused on the CoC and potential replacement chemicals (rather than all ingredients in the product) is an appropriate and very positive improvement.
- In the updated proposal, the focus on a product-chemical combination being the priority product goes a long way to minimize the potential for a regulatory treadmill – when the chemical of concern is successfully replaced, the product is no longer a priority.

In GMA comments on the July 2012 proposal, numerous serious concerns were raised that we continue to believe will prevent the overall program from being a deliberate science-based effort, focused on real improvements in the safety of consumer products. Despite the noted improvements, some post-hearing changes raise additional troublesome concerns and, where changes were made, they frequently do not go far enough to address the previously raised concerns. Some aspects of the updated proposal will not only be impractical and unworkable, but may result in arbitrary decisions and may stifle innovation. The regulations will impose unnecessary costs and administrative burdens on companies doing business in California and will require a large DTSC staff to manage the paperwork and process, even if the number of products is limited. The net result of the changes is to further establish the basis for a potentially arbitrary and precautionary approach that will not improve public health and the environment. The following are some issues of major concern to GMA, addressed more fully together with specific recommendations in the attached detailed comments:

- The updated proposal fully eliminates the concept of *de minimis* as a consideration, making the regulation completely unworkable for businesses. While the incorporation of the terms “intentionally added” and “contaminant” are welcomed, there is absolutely no practical benefit from the inclusion. Contaminants must be below the Practical Quantitation Limit (PQL)—in essence if the presence of something can be measured, it’s no longer a contaminant—otherwise the product would be subject to an AA. With no practical safe harbor level the proposal is unscientific and inconsistent with standards set elsewhere in federal and international chemical control systems. It provides no certainty for responsible entities to comply with the regulation. This is a clear indication that California is not open for business, nor for products that are safe for people and the environment.
- GMA has previously raised concerns about the non-quantitative product-chemical prioritization process, a so-called ‘narrative process’, which is not a suitable standard for identifying high priorities that can make meaningful improvements to public health and the environment in California. Several changes have weakened the process to the point where virtually any ingredient in any product could arguably be selected as the product-chemical combination. Those changes included definitional changes making “adverse impacts” equivalent to “adverse effects”; an increased emphasis on “presence” as an exposure criterion; the shift from the term “ability” to cause effects to “potential” to cause effects; enabling a narrow and limiting approach in considering available hazard

and exposure information on a product chemical combination; and the elimination of language in the “Key Principles” that has been in every previous regulation draft “...potential for exposure in quantities that would contribute to or cause adverse impacts...”. Taken together, these changes make for a completely unpredictable regulatory process and no certainty for businesses in California.

- The updated proposal continues to neglect the inclusion of an opportunity for a manufacturer to demonstrate the safety of a priority product through an analysis of the hazard of and exposure to the chemical from product use and disposal – a “safety case”. Enabling such an opportunity would create an approach that would provide a capability for making compliance with the AA requirements unnecessary by showing that the priority product does not create significant adverse impacts and is safe for humans and the environment.
- GMA previously raised concerns on the Trade Secret section related to the protection of Chemical Identity. The change in the updated proposal to allow non-disclosure agreements as a reason for a claim is a step in the right direction. However, the other change, which would allow a claim if a patent was applied for, makes clear that there is little appreciation for the distinction between trade secrets and patents. Chemical identity is often is a core trade secret for a product where the chemical is critical to product performance, quality, safety and cost and is rarely if ever patented. Chemical identity should always be claimable as trade secret, particularly in this case where the claim will be related to the development of alternatives for a priority product.
- GMA appreciates that the upfront insertion of the statutory language that prohibits DTSC from superseding other state and federal regulation. However, the Department continues to maintain complete discretion to determine whether its regulation “would provide equivalent or greater protection”.
- GMA is extremely concerned about the elimination of an exemption from the regulation in the updated proposal - the exemption for products in the supply chain of statutorily exempted products. DTSC does not have authority to regulate the supply chain of exempted products and such action would be superseding the regulatory scope of other agencies, which is prohibited by the statute.
- The definition for “reliable information” is somewhat improved in the updated proposal by adding a description of criteria for what would be viewed as ‘trustworthy’, although this would be a unique to California approach as opposed to the globally accepted approach for determining the reliability of studies. Also, the dependence on the “most protective” and chemicals with the “greater amount of information” have been eliminated and GMA supports this change. However, the proposed definitions for “reliable information” for “reliable information demonstrating the occurrence of exposure” continue to be a concern due to the absence of emphasis on weight of evidence evaluation and the focus on chemical presence, which is not the same as exposure. Not utilizing a weight of evidence approach and not considering actual exposure violates standard scientific protocols used in other California, US and International regulatory programs and will preclude the potential for California Green Chemistry’s program from building a reputation as a meaningful, science-based program.
- While the elimination of the Certified Assessor and Accreditation Body concepts is a warmly welcomed change, GMA is greatly concerned by the addition of a public comment process on all but Final AA Reports. This is a regulatory program and any review should be the duty of the regulator – DTSC. Public comment cannot possibly be based on complete information, as most if not all AA reports will have significant amounts of redacted Trade Secret information, only available to DTSC. In addition, public review creates serious and unnecessary competition-law concerns.

- GMA strongly objects to the proposed regulations because they would impose significant burdens on businesses that import their products into California, which vastly outweigh any purported legitimate benefit. California lacks authority to set the “rules of the game” governing the interstate and international market for consumer goods sold in California in a manner designed to benefit California economic interests.
- Critical workability concerns in the AA section continue - timelines are too short; the absence of focus on consumer acceptance; limited economic feasibility criteria; and the new requirement on external economic impact analysis.
- A previously raised concern in Alternative Analysis is the requirement to submit information on a manufacturer’s “operating margin”, which would unnecessarily require a company to completely open up its books to the public. This seems to assume that higher cost alternatives can be priced higher in the marketplace – this is absolutely not the case. Rather, a straightforward focus on the difference in cost to produce an alternative product is adequate to address the “economically feasible” question.
- Manufacturers are required to provide a listing of all retail sales outlets in AA reports – clearly proprietary information that goes beyond DTSC’s statutory authority.

California deserves a credible, workable, and successful program that can achieve this part of the Green Chemistry Initiative’s objectives, to complement the other five planks of the Initiative. GMA strongly supports noted improvements in the proposed regulations but still has many important concerns. There is much work remaining for the regulations to achieve the balance of being practical, meaningful and legally defensible. GMA is a member of the Green Chemistry Alliance (GCA) and supports the Alliance’s forthcoming detailed comments. In addition, GMA is a member of the Food Packaging Coalition (FPC) and supports the Coalition’s comments.

The Grocery Manufacturers Association remains committed to assisting the Department in developing and implementing a Green Chemistry program that will not only achieve the Green Chemistry Initiative’s objectives, but that will also be a model for the U.S. and elsewhere. If you have any questions or comments, please feel free to contact us. We look forward to our continued work together on this important public policy initiative.

Sincerely,



John Hewitt  
Director, State Affairs  
Grocery Manufacturers Association  
1215 K Street, Suite 1700  
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916-508-6278

cc The Honorable Matt Rodriguez, Secretary, CalEPA  
Miriam Ingenito, Deputy Secretary, CalEPA  
Kristin Stauffacher, Assistant Secretary, CalEPA  
Debbie Raphael, Director, DTSC  
Odette Madriago, Chief Deputy Director, DTSC  
Jeff Wong, Deputy Director Science, Pollution Prevention & Technology, DTSC  
Mike Rossi, Senior Business & Economic Advisor, Office of the Governor  
Cliff Rechtschaffen, Senior Advisor, Office of the Governor

## Detailed Comments

### Overarching Issues

#### **Prioritizing Product-Chemical Combinations.**

GMA supported the passage of AB1879/SB509 on the basis that their implementation would work to achieve significant improvements to public health and the environment by placing decisions about product safety in the hands of DTSC scientists. The key for success in this venture will be the way in which prioritization is structured. Prioritization – answering the question of what to work on – is central to any accomplishments that will be derived from the legislation. DTSC must employ a rigorous scientific process for selecting priority product-chemical of concern combinations. Given this strong appreciation for prioritization, GMA developed and provided to DTSC a proposed prioritization approach that draws on sound scientific principles and on successful approaches being followed in Canada, where 500 high priority chemicals have already been assessed and risk management action taken where appropriate. The proposed process is “quantitative”, considering a chemical’s level of hazard and the estimated potential for exposure through the use and disposal of the product being evaluated. By employing such a process across any number of product-chemical combinations, a relative ranking could be developed to assist in identifying high priorities for selection. This is posted on DTSC’s website under the headline “Chemical/Product Prioritization Resources” <http://dtsc.ca.gov/SCPResources.cfm>

Unfortunately, the Department rejected this proposal and instead has proposed a non-quantitative product-chemical prioritization process. It is a so-called ‘narrative process’, which is not an appropriate standard for identifying high priorities that will make meaningful improvements to public health and the environment in California. The process outlined has two aspects:

- Statement of Key Prioritization Principles
- Identification and prioritization based on adverse impact (effect) and exposure information plus consideration of other regulatory programs and the existence of safer alternatives.

GMA continues to appreciate a number of elements of the process and strongly encourages the Department to include them in the final regulations.

- The process considers both hazard and exposure in setting priorities.
- Key Prioritization Principles (previously Key Prioritization Factors) have now been placed at the beginning of the section and require Priority Product/CoC combinations to meet both Principles.
- The inclusion of “frequency, extent, level and duration” in § 69503.3 (b)(3)E which describes the approach for quantifying exposure via use and end of life scenarios. The one important exposure descriptor missing in this sentence is “route” of exposure, which is a critical consideration in determining the potential for adverse impacts. **GMA recommends that “route” be added in this sentence.**
- The concept of a Priority Product Work Plan outlining the Department’s direction for 3 year periods which helps in providing program focus as well as increasing manufacturer certainty.

Nevertheless, in the updated version, several changes have weakened the process to the point where virtually any ingredient in any product could arguably be selected as the product-chemical combination. Thus, the Proposed product prioritization process has become even

more problematic, both in the direct description in § 69303.3 as well as in the definition of important terms that describe the process. Taken together, these approaches make for a completely unpredictable regulatory process and no certainty for businesses in California. Specific concerns and recommendations:

- Numerous definitional changes have been made in the various “adverse impacts” definition to make those terms equivalent to “adverse effects”. “Adverse impact” as used in the statute and in OEHHA’s hazard traits, incorporates the concept of magnitude and extent of a hazard property. “Adverse effect” focuses solely on the particular hazard endpoint with no broader consideration. While every chemical has numerous measurable ‘effects’, only some have significant adverse impacts under certain conditions of exposure. **GMA recommends that all adverse impact definitions eliminate the term ‘effect’, replacing it with ‘impact’ per the statutory basis.**
- The term “potential”, which had been largely dropped in the July 2012 proposal (e.g. potential adverse effects, potential exposures, etc.), has been added to virtually every definition, prioritization criterion and consideration. This could drive a loss of focus in the process and lead to being overwhelmed with all manner of hypothetical scenarios. This change is somewhat mitigated by the addition of a definition for potential – “...that the phenomenon described is reasonably foreseeable based on reliable information”. The Department needs to concentrate focus on expected and probable health and environmental concerns, not every imaginable possibility. **GMA recommends that the definition of the term ‘potential’ include the concept of likelihood, e.g. “...that the phenomenon described is likely and reasonably foreseeable based on reliable information”.**
- In the updated narrative standard, § 69503.2 (b)(1)A, the Department is required to consider “...one or more of the factors listed in § 69503.3 (a) and one or more the factors listed in § 69503.3 (b)...”. The references are to a variety of adverse impact and exposure factors. In addition, this “one or more” construction is utilized in the referenced section § 69503.3 for both (a) and (b). This statement is not logical – the Department should be required to consider all of those factors where there is available information, and not jump to conclusions based on just one factor. This does not require all information to be available, in fact the proposal specifically says “...for which information is readily available”. **GMA recommends that the term “one or more” be stricken from all of its uses in § 69503.2 (b)(1)A, § 69503.3 (a) and § 69503.3 (b) so that all factors for which there is readily available information would be considered in the identification and prioritization process.**
- In the updated narrative standard, a vital phase has been eliminated from the Key Principles that has been employed in every previous regulation draft. It establishes the demonstration of potential for exposure to the chemical in the product “..in quantities that would contribute to or cause adverse...impacts”. This is a critically important part of the Principle and should be reinstated. The exposure factors in § 69503.3 (b) are very broad-based and all are relevant, however, the focus in the exposure criteria often seems to be on ‘presence’, ‘contact’ and ‘occurrence’, which are not the same as exposure. This suggests an entirely qualitative evaluation, which could result in opinions and emotion driving the process, potentially resulting in arbitrary decisions rather than a deliberative scientific effort to identify high priorities—i.e., real and significant threats to public health and the environment. Qualitative information, while directionally helpful in indicating existence, occurrence, contact or presence, cannot be sole factors in determining whether a situation creates an exposure with the potential for adverse impacts. Presence does not equate to significance, thus quantitative information demonstrating exposures at levels of concern must be a primary driving factor in priority

setting decisions. The one provision that previously mitigated this concern was in the previously “Key Prioritization Factors” (Now Key Principles”) area. **GMA recommends that the underlined phrase be reinstated in the Principles, § 69503.2(a)(2) - “There is significant ability for public and/or aquatic, avian or terrestrial animal or plant organisms to be exposed to the Chemical(s) of Concern in the product in quantities that would contribute to or cause adverse public health or environmental impacts”.**

- The updated proposal includes the concept of intentional ingredients, those chemicals purposefully included in a product to perform a function. GMA has maintained that the program will be most successful with a focus on those and welcomes the addition. A focus instead on chasing unintentional trace levels that have no adverse impact will significantly diminish the public health and environmental benefits of the program. DTSC seems to make its intent clear in presentations, identifying example priority products with chemicals of concern that are intentionally added to perform a function in the final product. Products that contain Candidate Chemicals should not be designated as Priority Products if such substances are present because of typical low-level impurities in raw materials that are well-controlled and not a concern for safety yet are not economically feasible to completely remove. **To ensure that prioritization is focused on substituting chemistries that are most likely to have the greatest potential risk to the public, GMA recommends the regulation make clear in § 69503.2 that chemicals considered in product prioritization decisions should have been intentionally added and have a function in the product.**
- The final prioritization concern relates to a step that is missing in providing comments on proposed Product-Chemical combinations as part of the APA process. DTSC is faced with considering potential regulation across the scope hundreds of thousand of products. Even after the program is underway for some years, there is little hope that there will be deep Department expertise spanning all of the products that may be considered for regulation. It’s understandable that product-chemical combinations could be selected which do not in fact represent the potential for adverse impacts through exposure to the product during use and disposal. There should be an explicit mechanism in the APA process, which would authorize the manufacturer, based on their expertise and knowledge, to provide information about the hazards, and exposures of the product – a “safety case” – and in that way can demonstrate the product’s safety and lack of adverse impact through manufacturing, use and disposal. Enabling such an opportunity would create an approach that could provide the Department with previously unknown information to alter the prioritization decision and/or make compliance with the AA requirements unnecessary by showing that the priority product is safe for humans and the environment. There are numerous examples of regulatory processes to establish the hazard, exposure and safety of ingredients in consumer products. One such example can be found at Federal Food, Drug, and Cosmetic Act Sections 201(s) and 409, and more specifically in FDA’s implementing regulations 21 CFR 170.3 and 21 CFR 170.30. **GMA recommends that a process be added in 69503.5 (b), which enables responsible entities to submit and requires DTSC to review product safety rationale as to why a particular product-chemical combination should not be a Priority Product and need not continue into Alternative Assessment.**

One final note – in identifying and selecting Priority Products, the Department should use a standardized product nomenclature system. The Revised ISOR makes reference to the GS1 Global Product Classification (GPC) system (<http://www.gs1.org/gdsn/gpc>) when describing Section § 69503. GMA agrees that the GS1 GPC is the appropriate source for describing products and that Priority Products should be identified at the Brick Level. Priority Product categories should be described at the Class Level for the purposes of the Department’s Priority

Product Work Plan. **GMA recommends that the Family level not be used – it is much too broad to provide any certainty and predictability for businesses, which is a key objective of the Work Plan concept.**

**AA Threshold – *de minimis*.**

The updated proposal completely eliminates the concept of *de minimis* as a consideration, making the regulation completely unworkable for businesses.

GMA as well as most business interests have consistently advocated for the inclusion of a *de minimis* threshold in the regulation with a default level of 0.1%. With ever improving analytical capability and ever-lower detection limits, vanishingly small and insignificant levels can be identified. These are great for generating headlines, but generally meaningless in protecting public health. Meanwhile, some stakeholders have suggested that “0” is an appropriate threshold. “0” of course is impractical – a technically impossible regulatory standard to measure and comply with, which provides no additional benefit to public health and the environment.

In all of the early iterations of drafting regulations, the Department provided a default level, multiple default levels or a process to identify a science-based default level depending on the hazard trait of the chemical of concern. In the updated proposal, the Department has completely shifted to the impractical position of other stakeholders. The revised approach begins appropriately by distinguishing between intentional ingredients and contaminants – a welcome addition that the business community has supported from the start. Intentional ingredients would be in scope for regulation at any level in the product – this is a stringent requirement, and takes no consideration of product safety and adverse impact into account. But under the updated proposal, contaminants must be below the Practical Quantitation Limit (PQL), otherwise the product would be in scope to be subject to an AA. In essence if the presence of something can be measured, it’s no longer a contaminant. It means that the effective *de minimis* level is “0” – anything that is measurable, down to one molecule could put a product into the scope of the regulation.

However, PQL is a procedure to determine the quality and validity of an analytical laboratory measurement. It is not appropriate to use PQL as an indicator of safety or absence of adverse impacts. Further, the use of the PQL creates a lack of both clarity and certainty for the regulated community. There are several reasons why the PQL is an inappropriate value to be used to establish the Alternatives Analysis Threshold (AAT). The PQL is a relative value that is dependent upon the analytical method and the material being tested. The DTSC should recognize the PQL for any given chemical of concern can vary based on the matrix in which the chemical is contained. This matrix can impact the degree to which the chemical can be detected as well as the appropriateness of any given analytical methodology to detect the chemical. Additionally, the PQL can and does carry a variety of definitions in practical application. The Department’s choice of PQL as an AA Threshold is in fact a policy decision of the most extreme case. This approach does not meet the Director’s objective of “Practical, Meaningful and Legally Defensible” regulation.

Threshold provisions are standard in a variety of chemical and product safety laws. Europe’s REACH chemical law applies a 0.1% *de minimis* level as a default in products. REACH’s 0.1% *de minimis* applies broadly, even to so-called Substances of Very High Concern that become banned in Europe. The European cosmetic directive also includes a 0.1% *de minimis* level for over 1300 carcinogens and reproductive toxicants. This same level is also used in worker and transportation regulations in Europe and North America. GMA believes that California should

be consistent with other national and international laws. The basis for these laws is that low, but measureable levels in consumer products do not lead to the likelihood of harm because exposure levels are so low.

In addition, GMA has supported the concept that DTSC should be able to adjust the threshold from the default based on sound science and reliable information. Experience in the European Classification system (EC No. 1272/2008) is that for 85% of the over 4000 chemicals with classified hazards, the threshold is 0.1%; for the remaining 15% the EU has determined a different level—sometimes lower and sometimes higher. This covers all hazard traits, including those that are applicable in DTSC's most stringent provision.

The updated proposal eliminates the adoption of a default threshold or a case-by-case threshold determination and replaces it with no threshold at all. GMA adamantly disagrees with this direction. Neither the regulations, nor DTSC, should presume that the mere presence of an identified Candidate Chemical or CoC is reason to suggest adverse impact and potential harm. With no practical default level the proposal is unscientific and inconsistent with standards set elsewhere in federal and international chemical control systems. It provides no certainty for responsible entities to comply with the regulation. This is a clear indication that California is not open for business, nor for products that are safe for people and the environment. **GMA respectfully requests that the Department reconsider establishing the *de minimis*/AA threshold in the final regulations at 0.1% for all hazard traits, consistent with established national and international approaches and with the capability for DTSC to set a different level on a case-by-case basis. If a default threshold is not established, GMA believes that a discrete, non-zero threshold should be set by DTSC for each product-chemical combination on a case-by-case, independent of whether the chemical is a contaminant or ingredient. As part of the APA process, responsible entities for the product-chemical combination could provide data and a rationale for establishing the threshold level in the same way as suggested earlier for the "safety case", demonstrating the safety of a product/COC combination – the lack of significant adverse impact. If manufacturers can demonstrate the safety of their product, the product should not be required to complete the AA process.**

#### **Regulatory Duplication.**

GMA welcomes several improvements in the updated proposal. Statutory authority and limitations in this area are now partially noted upfront in Article 1. The exemptions provided statutorily for certain products are acknowledged and a 'harmonization' provision is added attempting to address a statutory prohibition on superseding other regulatory authorities. However the update does not go far enough and raises several serious concerns that this regulation could create conflicts with products and devices that are regulated under other authorities. The proposed regulation goes beyond the statute to assert Department dominance where it believes it would provide a level of public health and environmental protection that is equivalent to or greater than the protection that would potentially be provided if the product were not listed as a Priority Product. It is essential that any applicability of the Safer Consumer Products regulation not conflict with, impede or frustrate other regulatory schemes or systems by which products are currently regulated. In this regard, regulatory duplication for any product should be an upfront and straightforward question in the applicability stage of the regulation – is the potential health or environmental impact from the chemical in the product regulated by another regulatory agency or not? If it is regulated by another agency, then it should not be in the scope of the proposed regulation. Specific concerns and recommendations:

First, previous language that appropriately exempted products in the supply chain of exempted products has been deleted. This suggests that the Department believes that it can select a priority product-chemical combination upstream in an exempted product supply chain. DTSC does not have this authority and such action would be superseding the regulatory scope of other agencies, which is prohibited by the statute. For instance, the statute exempts food as defined in Section 109935. Section 109935 states: “Food” means either of the following: (a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal. (b) Any article used or intended for use as a component of any article designated in subdivision (a). Thus, all materials in the food supply chain are considered to be food and all are exempt under the statute. Pesticides and the pesticide supply chain are similarly exempt. **GMA recommends that the strike-through in § 69501 (b)(2) be restored to the proposed regulation: “...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”.**

Second, the Harmonization language is not faithful to the statute, SB 509 (Simitian, 2008), which states: “This article does not authorize the department to supersede the regulatory authority of any other department or agency”. The updated proposal speaks to “superseding the requirements” of another program. **GMA recommends that the statutory language be used directly so that there is no confusion.**

Third, the updated proposal does not acknowledge the other prohibition in the statute – “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”. **Again, so that there is no confusion, GMA recommends that this language be inserted in Article 1.**

Finally, there appears to be a conflict within the regulation. In §69501 (a)(3)(A)2 the decision standard is stated as “...protection that is equivalent to or greater than...”. In §69503.2 (b)(2) it is stated as “...determines that the listing would meaningfully enhance protection...”. These are two very different standards for determining the Department’s dominance, the latter being a more functional and clear-cut differentiation for decision-making. The former, by including equivalency suggests that there would be value in having increased regulation that would only achieve the same result, which would clearly be duplicative and not appropriate. **GMA recommends that the conflict and potential confusion be eliminated by utilizing the “...meaningfully enhance protection...” standard in both sections of the regulation.**

### **Science-Based Processes.**

To build confidence in the Green Chemistry Program, DTSC must operate the program with a rigorous, science-based approach, in concert with state, federal and international best practices. This must be implemented in the identification of Candidate Chemicals, the selection priority products and associated chemicals of concern, in the AA process and in determining regulatory responses. The proposed regulations raise significant concerns that there is no intention to do so, but rather there is a goal to structure a system that could pander to the latest sensationalist junk science story. The concerns start with the use of the narrative standard (weakened in the updated proposal), which is ultimately subjective and facilitates a political, not scientific, basis for prioritization. The concerns are furthered by inadequate definitions for “reliable information” and “reliable information demonstrating the occurrence of exposure”, which do not require a standardized mechanism to assess the quality and reliability of information, but rather the fact that someone has just put it into the public domain. Finally, there is no

discussion on the use of a weight of evidence process in situations where there are multiple studies for a single endpoint,

In evaluating information to make decisions and substantiate conclusions on Candidate Chemicals, priority product-chemical combinations, alternative assessment, and regulatory responses, DTSC and responsible entities should be guided by the following principles:

- DTSC’s decision-making process shall meet benchmarks of objectivity, transparency, and scientific accuracy needed for stakeholders to have sufficient confidence in their use for health and environmental regulatory decision-making.
- All evaluations – by DTSC in determining Candidate Chemicals, priority products and associated chemicals of concern, AA Thresholds and regulatory responses; and by responsible entities in conducting alternative analyses – shall rely on the best available scientific information regarding possible hazards and risks of substances, and employ consistent, objective methods and models to derive realistic determinations of hazards and risks at environmentally relevant levels of exposure.
- Transparent criteria shall be established upfront and then consistently applied throughout the evaluation process to identify studies, and to evaluate their quality, relevance, and reliability.
- All evaluations shall be based on a framework that takes into account and integrates all relevant studies while giving the greatest weight to information from the most relevant and highest quality studies.
- Hazards and risks shall be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges; it is not sufficient to rely on theoretical maximum exposure estimates to characterize potential risks. The characterization should provide a full picture of what is known and what has been inferred, and should also present results based on alternative plausible assumptions.
- Assessments shall provide full disclosure of key information. When assumptions (or policy preferences) are used in lieu of scientific data, the assumptions (and policy preferences) must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.

**GMA recommends that DTSC incorporate these principles into Article 1 of the regulations to provide an overall theme and foundation for science-based implementation.**

#### **Interstate Commerce.**

GMA continues to strongly object to the proposed regulations because they would impose significant burdens on businesses that import their products into California, which vastly outweigh any purported legitimate benefit. This concern was raised previously in GMA comments of October 11, 2012 and no changes in the updated version fully address the issue. The Regulations impose burdens on the import of goods into California by requiring a detailed analysis not only of the contents of the products, but also the manner in which these products were produced and transported to California. DTSC acknowledges that “[r]esponsible entities will bear real costs as a result of these regulations,” but that “[s]ince most product manufacturing takes place outside California,” the expected “direct short-run California employment impacts [would] be minimal.”<sup>1</sup> Indeed, DTSC has adopted the view that “California

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<sup>1</sup> Matthew E. Kahn, *Economic Analysis of California’s Green Chemistry Regulations for Safer Consumer Products*, at 4, 5 (Mar. 2012) (“*Economic Analysis*”).

firms have an edge in gaining . . . market share” for developing “greener alternatives” under the Regulations. *Id.* at 5. According to DTSC, the Regulations establish “new ‘rules of the game’” governing the import of products in California. Under these “new rules,” “California’s firms are likely to [be] among the most nimble in responding and thriving in the new regulatory environment.” *Id.* at 9. California lacks authority to set the “rules of the game” governing the interstate and international market for consumer goods sold in California in a manner designed to benefit California economic interests.

The Regulations should not be adopted because they impose substantial barriers to the California market by allowing DTSC to co-opt the decisions of California consumers and authorize DTSC to dictate whether or not products – including safe products – can be marketed in California based on, for example, the manner in which they are manufactured outside California. *See Economic Analysis*, at 9 (acknowledging that some products “are likely to be banned”). The Regulations authorize DTSC to deny California residents the opportunity to decide whether to purchase a product based on DTSC’s assessment of the manner in which the product was produced or whether another means of production would render a competing product economically feasible. These Regulations impose significant costs on manufacturers that must bear the burden of testing their products, conducting alternative analyses, and then complying with the regulatory response dictated by DTSC. These barriers especially harm small businesses that lack the resources to comply with these burdensome regulations.

In contrast, there are limited, if any, benefits from the Regulations. Chemical ingredients in consumer products already are subject to regulation at the national level by the Toxic Chemical and Substances Act administered by US EPA and the Federal Hazardous Substances Act as well as other statutes administered by the Consumer Product Safety Commission. Likewise, federal law prohibits the marketing of adulterated cosmetics – i.e., cosmetics that contain any poisonous or deleterious substance that may render them injurious – under the Federal Food, Drug and Cosmetics Act. 21 U.S.C. § 361. In addition to these national, uniform standards, manufacturers already have strong incentives to ensure that their products are safe and effective both by market mechanisms through which consumers, presented with a choice, will purchase products with safer ingredients as well as remedies to consumers injured by products that are actually unsafe. The proposed regulation seeks to replace these existing protections and informed consumer choice with local government mandates. Indeed, DTSC has made no effort to demonstrate that the burdens imposed by the Regulations remotely justify the substantial costs that DTSC acknowledges that would be imposed on importers of products into the California market.

## Specific Issues

### §69501.2 Definitions

**Chemical ingredient** – A chemical ingredient is one that serves a necessary and intended function in the final product. However, as currently defined in the proposed regulations, chemical ingredient overlaps with the definition of chemical creating the basis for confusion. Additionally, contaminants could be considered as a “chemical ingredient”. We would point out that in the definition of “Component”, DTSC has recognized the concepts of necessary and intended and there should be a parallel approach for formulated products. **GMA recommends the following revision: “Chemical ingredient” means a chemical that is a necessary or intended element and serves an intended function in a consumer product.**

**Legal requirements** - Regulations in other states or countries continue to be not acknowledged in the proposed regulation. For instance, many products are made for the North American or even global market. **GMA recommends the following alteration to the definition. “Legal requirements” means specifications, performance standards, and/or labeling requirements that a chemical, product or product packaging is required to meet by federal or California or other state or international law.**

**Reliable Information** – While there are some helpful improvements to this definition, the fundamental problem has not been resolved.

The definition for “reliable information” is improved in the updated proposal by adding a description of criteria for what would be viewed as “trustworthy”. Also, the requirements on “most protective” and “greater amount of information” have been eliminated. The addition relating to study design hypothesis also makes sense. However, there remain two major concerns with the approach.

First, the proposed definitions for “reliable information” and for “reliable information demonstrating the occurrence of exposure” continue to be a concern due to the absence of emphasis on weight of evidence evaluation. What would DTSC do in a case where there are four peer-reviewed studies that provide entirely different results, or four studies from a variety of the listed sources that come to different conclusions? By the Department’s current definition they are all “reliable information” – there is no reference to a weight of evidence process. **GMA’s recommendation for this issue was offered earlier, the “Science-Based Processes” section of these comments – that a set of scientific principles be set forth in Article 1, including a statement on use of “weight of evidence”.**

Second, in adding the ‘trustworthy’ criteria California is inventing its own unique system for determining the reliability and relevance of information. This will take time and effort by the Department to make such judgments under its unique system. This is in opposition to the statute, which directs the Department to “...use, to the maximum extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes”. The need for a mechanism to judge studies for relevance and reliability is widely recognized by federal agencies with health and safety responsibility and in international fora. As a result, the Organization for Economic Cooperation and Development (OECD) has developed a globally accepted method for rating the quality and reliability of studies. This methodology has been used for determining data quality and reliability on tens of thousands of studies for over 2000 chemicals in US and OECD HPV programs. Hundreds of thousands of studies on over 5000 chemicals have been submitted to

REACH that were rated according to this approach. The same is to occur for additional thousands of chemicals in 2013 and future years. The methodology is published as Chapter 3 in the OECD's Manual for Investigation of HPV studies.

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

**GMA reiterates our recommendation that the department establish the OECD approach as a standardized mechanism for judging data reliability in the regulations by subjecting studies to this definition for “Reliable Information” based on the OECD Manual:**

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

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

An additional note, GMA supports one aspect of the definition of reliable information demonstrating exposure – (58)(D), considering exposure or modeled point concentrations associated with adverse impacts. This comparison of hazard and exposure information to indicate the potential of harm makes great scientific sense. The updated proposal is consistent on this point in (58)(E) on monitoring data indicating presence of a chemical “...in concentrations or volumes...” that can cause impacts. It is only when exposure concentrations associated with adverse impacts occur that there is a concern for public health and the environment. **To be consistent and scientifically sound, GMA recommends that similar language be added to (A), (B), and (C) in this definition.**

#### **§69502 Candidate Chemicals Identification**

The Proposed Regulation starts with a consolidating a list of chemicals from 23 source lists at the effective date of the Regulation, resulting from the merging of all the items on the lists. In fact, these lists contain well over 4,000 distinct chemicals. DTSC has indicated that the list it will publish will be narrowed to 1200 chemicals, but does not indicate how the reduction will take place other than indicating that it will take out the approximately 450 pesticides and pharmaceuticals that are exempted from the regulation.

As previously indicated, GMA welcomes the shift to calling the initial list “Candidate Chemicals”.

DTSC has not indicated whether Chemical Abstract (CAS) numbers will be used to identify each chemical on the list. GMA cannot support a list that contains chemical group names. This regulation must specify unique Chemical Abstract Services numbers (CAS RN) and cannot utilize generic chemical categories. For instance, the perfluoro chemical category contains many hundreds of different unique CAS RN chemicals, each with it’s own properties. The ability to comply with and to enforce the regulations requires the clarity of a unique CAS RN associated with chemical of concern lists, priority product determination, AA threshold concentrations, the conduct of AA’s and regulatory responses. **GMA recommends that the regulation require the Department to list Candidate Chemicals by their Chemical Abstract number.**

**Prioritizing Candidate Chemicals.** Actual prioritization of chemicals considering both hazard and indicators of exposure gives credibility to the process. In the long term it will conserve Department and regulated community resources; and the statute mandates it. As noted in the earlier, the proposed regulations at § 69503.6(a) describe an approach that the Department indicates will identify approximately 230 Chemicals of Concern for the initial focus in the program through 2016. GMA strongly supports the concept behind this approach, which uses information on chemical hazard together with indicators of exposure to narrow the field. This is a critically important step forward, highlighting a core group of substances to make progress on in the initial years of the program, while sending an important signal to the marketplace on a more tightly focused list. However, it should not be a one time arrangement, rather there should be a periodic process to identify a narrowed list on the basis of hazard and indicators of exposure. **GMA recommends that the regulation require DTSC to update the focus list of Candidate Chemicals beyond 2016 using the above process that considers both hazard and exposure information.**

GMA continues to recommend the following alternative approach to prioritize Candidate Chemicals to a narrowed and focused list. This can be completed in a timely way—within 90 days of the publication of the regulation—and not slow progress in implementing the regulations. The Department should:

- Begin with appropriate lists (that represent the work of authoritative bodies) to identify chemicals with significant hazards using deliberative scientific processes with the opportunity for stakeholder input and comment (§ 69502.2 (a) contains such lists: GMA concerns and recommendations on exception is below);
- Merge those lists to generate a set of “chemicals of interest”;
- Conduct an actual prioritization/screening to identify real Chemicals of Concern. This would encompass several steps:
  1. Clean up the merged lists—remove pesticides, pharmaceuticals, and other substances that are not chemical compounds to which the regulations apply.
  2. Narrow the result from above to identify chemicals made or imported into the U.S. using EPA’s 2012 CDR data, FDA and other exposure information such as biomonitoring data;
  3. Further narrow the result to chemicals used in consumer products in the U.S. using EPA, FDA and other information;
  4. Publish the proposed Chemical of Concern list for comment.
  5. Finalize the list.

This approach has several benefits: it can be done quickly without diverting DTSC’s other efforts to implement the regulation; it produces a large list of “Candidate Chemicals” that can serve as a broader marketplace signal, any one of which can readily become a Priority Product-chemical of concern combination; it produces a narrowed and targeted list of Candidate Chemicals not just to support DTSC’s further work, but that will be more likely to prompt action in the marketplace beyond just DTSC’s selected Priority Product-Chemical combinations; it will more likely have influence in other states and at the federal level, in contrast to the existing proposed approach naming thousands of chemicals, which will have no impact. It can be updated periodically based on new information on both hazard and exposure.

**Concerns on Source Lists.** As noted above, a variety of source lists are appropriate and will be useful as a starting point in a true prioritization process. GMA appreciates DTSC efforts to modify the previous proposed source lists to better represent the work of authoritative bodies that use deliberative scientific processes with the opportunity for stakeholder input and comment. GMA welcomes the deletion of the European Commission Endocrine Disruptor list.

GMA also agrees that the (1)(G) REACH SVHC PBT chemicals list represents an appropriate authoritative European source. There are several remaining concerns:

- (1)(H) is Canada’s prioritization list of potential PBT compounds, mostly based on modeling and completed in 2007. Since that time Environment Canada has conducted hundreds of assessments in its Chemical Management Program leading to determinations in a number of cases that a chemical is in fact NOT PBT. **GMA recommends that the Department utilize the most up-to-date information on these chemicals from Canada in establishing its Candidate Chemical list.**
- (1)(I) is the EU’s Category 1 respiratory sensitizers. While this represents an authoritative source, it raises a key issue for these and all other listed chemicals. All listings are based on information related to the route of exposure in relevant studies. In this case, it is the inhalation route. Chemicals listed due to one route of exposure, do not necessarily cause the same effect by other routes of exposure. **GMA recommends that the Department include, at § 69503.3 (b)(3)E, an evaluation of route of exposure information together with “frequency, extent, level and duration” as part of its identification and prioritization of Product-Chemical combinations.**
- (1)(J) is IARC’s Carcinogen list. GMA strongly disagrees with inclusion of 2B substances, as the evidence level is less than that of other international Carcinogen sources. **GMA recommends that IARC 2B substances not be included in Candidate Chemicals.**
- (1)(M) is the Office of Health Assessment and Translation reproductive and developmental toxicants. **GMA agrees with this source, but recommends that chemicals included as Candidates only be those identified as Serious Concern and Concern by OHAT. Chemicals identified as “Some Concern” should not be included.**
- (2)(D) has been updated to add the Clean Water Act section 303(d) as a source list. This had been proposed several years ago, then removed based on the fact that it leads to many unwanted anomalies—listing oxygen, color, nitrogen, iron, solids, aluminum, sulfates, etc. These are clearly not Candidate Chemicals in the context of the Regulation. Additionally, most relevant 303(d) listings are duplicated on other source lists. **GMA recommends that the CWA 303(d) list be eliminated as a source list.**
- (2)(F) is the California Biomonitoring program, where numerous chemicals have been listed, many of which are beyond those tested in the CDC Biomonitoring program. The California program is in the early stages, and only limited testing has been completed and validated. **GMA recommends that chemicals that are beyond CDC’s studies and which have not yet been tested and validated in California’s program NOT be considered to have “exposure information” under this regulation and that the California Biomonitoring program only contribute to the initial Candidate Chemical list those substances that have been tested and validated as of the date of issue.**
- (2)(H) is the OSPAR list of substances for priority action. **GMA recommends that this list be dropped, as it does not meet the authoritative body criteria of being a deliberative scientific process with stakeholder input.**

**Adding Entire Chemical Lists.** Article 4 allows Petitioners to request the addition of entire lists of chemicals. GMA opposes this approach. **GMA recommends that new Candidate Chemicals be individually petitioned and considered on a case-by-case basis, considering the availability of reliable information on hazard and indicators of exposure.**

#### §69503 Product Prioritization

In addition to the significant comments on Product Prioritization offered earlier, the following two areas should be noted.

**Exemption Notification.** GMA supports the change that eliminates exemption notifications. This eliminates a potentially large paperwork burden for manufacturers not producing the product-chemical combination.

**Inaccessible Components are Not an Exposure Concern [Sections §69501.1 & 69503.2].** GMA appreciates the addition of a consideration of potential accessibility to the criteria for exposure consideration in § 69503.3 (b)(4)F. As DTSC acknowledges in their “Initial Statement of Reasons” (ISOR) [Section 69503.2], there is little if any exposure to a “Chemical of Concern” (CoC) from inaccessible components. However we stand by our view that “inaccessible components” should be defined and removed from prioritization. This approach is consistent with California’s statute, and similar laws regulating the presence of chemicals in products in Washington State, Maine and on the federal level under the Consumer Product Safety Improvement Act. **GMA recommends that DTSC go further to define “inaccessible components” and reference that in several key places in the regulation to prevent the regulations from overreaching and focusing on components where there is no reasonable likelihood of exposure.**

### §69505 Alternative Analysis

**Positive Aspects.** GMA continues to support the positive aspects of the draft regulations in regards to Alternatives Analysis (AA) that should be maintained as a part of the final regulation:

- Eliminating Certified Assessor and Accreditation Body and third-party verification concepts from the draft regulations.
- The scope of the Alternatives Analysis is focused on a specific Priority Product-chemical of concern combination serving as basis for listing a product as priority plus replacement chemicals and not all ingredients in the product.
- GMA welcomes the changes in the updated version that should eliminate the regulatory treadmill issue. Once an alternative is selected and implemented, the manufacturer would no longer be making the Priority Product, as long as the chemical of concern was replaced. This enables a situation that when definitive results have been achieved, the Department and the responsible entity can declare success. The company’s product will no longer be a Priority Product, and DTSC can move on to other product-chemical combinations.
- Alternatives Analysis is appropriately defined as “[A]n evaluation and comparison of a Priority Product and one or more alternatives to the product, under article 5”
- “Functionally acceptable” appropriately focuses on both product legal requirements and consumer acceptability. **However, GMA recommends that the alternative product should meet or exceed performance of the original product, not “sufficiently” perform.**
- AA is required for only those priority product-chemical of concern combinations that continue to be placed into the marketplace after the priority product listing.
- Provision eliminating the need for any further evaluation after the first stage of AA if the manufacturer claims that a “functionally acceptable and technically feasible” alternative is not available. Submission of an abridged AA report would be required within 180 days of the product being listed as priority.
- Inclusion of § 69501.2.(a)(2) and § 69505.1. (c)(1), wherein the requirements of this chapter applicable to a responsible entity may be fulfilled either entirely or partially by a

consortium, trade association, public-private partnership, or other entity acting on behalf of, or in lieu of, the responsible entity.

- Inclusion of a framework for an alternate AA process.
- Flexibility allowing the manufacturer to use the most appropriate methodologies, models, tools, and decision-making process to assess the product-chemical combination alongside potential alternatives, to make a determination of the selected alternative (within the context of the company's product position in the marketplace) and the opportunity to propose the most appropriate regulatory response.
- The allowance for a feasibility assessment after AA report submission, and opportunity to select a different alternative, provided that an updated report outlining the rationale for the change is submitted to the Department.
- Only relevant factors need to be considered further, while allowing the manufacturer to explain why other factors are not relevant to the analysis.
- GMA welcomes the updated proposal use of the term "material" as a criterion for determining relevance in the AA.
- The Two Stage tiered-process envisioned by DTSC is a useful approach. The Preliminary AA Report submitted after Stage 1 focuses on the function, performance, and legal requirements of the CoC in the PP and identifies and provides an initial comparison of potential substitutes for relevant impacts. The Final AA Report submitted after Stage 2 focuses on a comparative analysis at the product level integrating all relevant factors.
- Enabling the 'Consideration of Additional Information', allowing elimination of alternatives for 'showstopper' reasons in Stage 1.
- Qualitative as well as quantitative information can be provided for relevant factors.
- In addition, the focus on a product-chemical combination as the priority product eliminates the potential for a regulatory treadmill – when the chemical of concern is successfully replaced it is no longer a priority product.
- Providing manufacturers the necessary time to implement their alternative through specifying an Implementation Plan in the final report.
- Including the opportunity within the Implementation Plan to identify any steps necessary to ensure compliance with existing laws.
- A process to dispute most of the Department's decisions is established

### **Concerns in Alternative Analysis**

While some of the underlying themes within the updated proposal are appropriate and appear to be consistent with the existing product development paradigm, there remain many challenges and opportunities for improvements to help maintain focus of any required Alternatives Analysis.

**Public Comment on AA.** While the elimination of the Certified Assessor and Accreditation Body concepts is welcomed, GMA is greatly concerned by the addition of a public comment process on all but Final AA Reports. This is not appropriate for several reasons. First this is a regulatory program and any review should be the duty of the regulator – DTSC. Second, public comment cannot possibly be based on complete information, as most if not all AA reports will have significant amounts of redacted Trade Secret information – on economic, technical and functional topics – only available to DTSC. In addition, the requirement that AA reports be made available for public comment creates serious and unnecessary competition-law concerns. Specifically, because the AA reports are required to contain economic, technical and functional data, including a detailed review of the economic and technical feasibility and the functional acceptability of various considered alternatives, any public comment requirement essentially mandates the opening-up of competitively sensitive information to the horizontal competitors

of the Regulated Entity. Such sharing of competitively sensitive information creates potential exposure under the federal antitrust laws, and that exposure cannot be eliminated or minimized on the grounds that state law mandates the information sharing. In fact, the federal antitrust law on this topic is quite clear that potentially anticompetitive behavior cannot be shielded from antitrust scrutiny by state law unless the anticompetitive behavior is “clearly articulated and affirmatively expressed” by the state law. At the very least, the anticompetitive behavior must be a “foreseeable result” of what the state has authorized. In this case, the underlying legislation cannot meet any of these tests. Indeed, the underlying legislation is focused on traditional EH&S purposes and clearly aims to protect trade secrets; there is no clearly expressed intent to displace commercial competition, and such displacement is not a foreseeable result of the EH&S goals expressed in the underlying legislation. The Supreme Court has just recently reaffirmed all these federal antitrust law principles in the case of *Federal Trade Commission v. Phoebe Putney Health System, Inc.* (slip op. February 19, 2013) (holding that Georgia law creating local hospital authority did not express a state policy to displace competition through permitting potentially anticompetitive hospital mergers). Because the Regulated Entity would remain exposed to potential federal antitrust liability for knowingly sharing commercially sensitive information with its competitors, the proposed regulation could only be permissible if state law or at least a foreseeable result of state law mandated such information sharing, which is generally contrary to federal competition law policy. In this case, the underlying state law does not have a sufficiently expressed state policy in favor of information sharing by competitors, and such information sharing is not what one would reasonably foresee from a traditional EH&S statute. **GMA recommends that the provisions requiring public comment and Responsible Entity response to those comments be eliminated and that DTSC be the reviewing organization for AA reports.**

**Timeframes.** The timeframe described for preparing Alternatives Analysis reports (i.e., 6- and 12- months for preliminary and final reports, or 60 days and 18 months for AA workplan and final reports) is unreasonable and unworkable should there either be a need to do further experimental research to evaluate a particular alternative or be a desire for a consortium or public-private partnership approach to accomplishing the AA work. There are clear cases where industry-wide efforts have been shown to be the best way to address substitution. Despite the limitations discussed below, there are clear advantages in sharing some tasks and in encouraging economic viability of some otherwise questionable substitutions.

The Responsible Entity will need more than 18 months to identify one or more technically and economically feasible and functionally acceptable alternatives (even if it is initially a theoretical analysis), develop a safety profile comparison of the base and alternative together with other information on other relevant factors, do adequate market research and gauge consumer acceptance before selecting the most viable alternative, write the submission for the Department and get management approval to submit. Such innovation, when an alternative is not well known can require 3-5 years or more, often with many failed alternatives cast aside at different points in the product development process. For example, for a “simple” substitution in formulated products, a company at a **MINIMUM** would need two months to get scientists & engineers coordinated and in the lab; one year of research to find a material that meets safety and economic requirements, supply, etc. ; three months of process lab testing; six months for testing at the manufacturing plant (to include scheduling for an experiment since plants typically run at capacity); three months of consumer testing (note that not all products are used every day, and some products must be used multiple times for the consumer to notice something negative). From the time one or a few materials are identified for further assessment, on the optimistic side, **AT LEAST** 26 months is necessary for R&D and this is **ONLY IF** an EPA Pre-Manufacturing Notification (PMN) is NOT required. Realistically, a responsible entity should be

given 3 years, with the option to extend for another 2 years, plus an additional 1 year if a new chemical PMN is required (as the PMN work may sometimes be done with an R&D exemption).

However, in most cases, substitutions will be much more complex, and the product system may be more complex. Many substitutions will likely require multiple materials to be substituted for the one chemical of concern. A good example is the replacement of phosphate in auto dishwashing (ADW) products. While some companies continue to optimize the formula on phosphate replacement in ADW over the past 25 years, the initial replacement was accomplished in three years. Phosphate replacement required 4 to 5 different chemicals depending on the formulation, in which one of the materials required a PMN (and a New Substance Notification (NSN) in Canada), and another material an NSN.

Stage 2, although indicated by the draft rules as being a theoretical exercise, actually requires lab work to analyze physical alternatives and to help narrow down the list of potential alternatives. Innovation requires resources (i.e., people, finances, and equipment) and time (anywhere from months to years) depending on the size of the project and the complexity of the product. Once the lab research has been completed and the effect of the substitution on the product determined, the material has to be tested in processing labs to see if the new ingredient or series of ingredients can be processed. There are also requirements for compatibility and stability testing. Then, scaling up is necessary at a manufacturing plant. Meanwhile, market research for consumer acceptance is carried out – an iterative process - with relevant and realistic product/material (generated from a manufacturing plant) to ensure that consumer satisfaction is achieved with the final product. Additional special testing for specific claims or consumer tolerance in use may also extend the timeframe needed. Not only is the proposed timeframe inadequate for research and development, it is clearly inadequate to effectively get a new chemical TSCA-listed under EPA’s Pre-Manufacturing Notification (PMN) program.

As mentioned above, there will be situations where a collaborative approach is the best approach to pursue alternatives. Flexibility in timing and report submission is also prudent when the responsible entity is a consortium, trade association, or public-private partnership. Anti-trust requirements in the U.S. demand care in building such relationships, making them cumbersome since communication must involve a third party for oversight and blinding of most communication. It could take 3-4 months to build a consortium, before any analysis is done on a chemical of concern/priority product pairing. And, most likely, the analysis for both Stage 1 and Stage 2 will take more time for a consortium to complete (than for a product manufacturer). Thus, an additional provision should be included in which a consortium is permitted to form within one year of the priority product listing prior to any AA. The oft-repeated experience of the “flame retardants in circuit boards,” which is ongoing after more than 6 years, is instructive. Despite a widespread, committed level of interest and effort by the industry in this public-private partnership, there is not yet a fully demonstrated alternative that achieves the goal.

In summary, where an alternative is not readily available, not well known or not already broadly adopted, the 6- and 12-month timings are not workable. **GMA recommends that these timeframes be expanded to a minimum of 12 months for a Preliminary Report and 24 months for the final on individual company AA’s and 18 months/30 months for consortia. A tiered approach could be utilized considering the simplicity/complexity of the product system and the substitution, the availability of alternatives, the extent of research and development needed to identify and investigate alternatives, and whether a consortium approach is being used. Higher tier approaches could require an upfront Work Plan and regular reports to provide the department with updates on progress.**

**Focus on Designated Chemical of Concern and Alternatives.** A single Chemical of Concern (CoC) should serve as the basis for designating a product as priority and for the Alternative Analysis process. In the updated proposal as currently written, there is no limitation on the number of CoCs that could serve as the basis for designating a given product as priority. For example, the Department could identify FIVE CoCs as the basis to prioritize a given product. The subsequent AA would require a comparative analysis of all potential alternatives for each CoC in the priority product. The scope and breadth of the analysis would grow exponentially, ultimately leading to paralysis by analysis. To avoid “scope creep”, the focus of any analysis should be restricted to the single CoC that is the reason for the designation of the priority product. **To ensure a workable, pragmatic, and meaningful program, GMA recommends that the analysis focus only on ONE Priority Product-Chemical of Concern combination.**

**Consumer Acceptance as a Relevant Factor.** As mentioned previously, the AA should identify “relevant” factors, which are critical to achieving a focused and efficient AA process. Consumer acceptance is ALWAYS relevant and important. Although a manufacturer has the opportunity to consider consumer acceptance in the alternate AA process, this factor should be explicit among the factors listed in § 69505.4. (a)(2). **GMA continues to recommend that the following language be included in the regulations: (NEW) § 69505.4. (a)(2)(B)4. A determination of whether there is Consumer Acceptance of the alternative.**

**Economically feasible alternative.** On the determination of the “economically feasible” (§ 69501.1.(a)(29)), the current definition is: *“Economically feasible” means an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.* Manufacturer’s operating margin is not a good choice as a criterion for this definition. Operating margin goes well beyond the capital and operating costs to make a product and includes such factors as delivery cost, advertising costs, research and other overhead costs, etc. This economic feasibility should be focused on the impact of the alternative on the cost to produce a product. The draft regulations should additionally allow the responsible entity to also consider the *availability* of the “functionally acceptable” alternative, *affordability*, and the cost to produce the product. **GMA recommends that § 69501.1.(a)(29) be revised to:**

**§ 69501.1.(a)(29) “Economically feasible” means an alternative product or replacement chemical does not significantly increase the manufacturer’s cost based on the following:**

- 1. The extent to which a functionally acceptable alternative is currently available in the marketplace;**
- 2. The affordability of any currently available functionally acceptable alternative; and**
- 3. The cost differential to produce a product, including not only the actual material cost difference but also any difference in the processing/manufacturing conditions and capital investment, between the Priority Product and the alternative.**

**Economic Impacts.** Regarding economic impacts (§ 69505.6.(a)(2)(C)), accounting for all projected cost impacts for relevant exposure pathways during the life cycle segments of the product and the alternatives being considered to include among others *public health and environmental costs; costs to government agencies and others managing waste and overseeing environmental cleanup and restoration, or charged with protecting natural resources, water quality and wildlife* is so wide and far-reaching that it becomes nebulous and completely unclear how a manufacturer might account for these in any sort of standardized and broadly acceptable way. Moreover, traditionally, it is the responsibility of the government and not the manufacturer to assess the regulatory and macro/micro economic impact of chemical and product alternative regulations as it is government and not industry that is responsible for making public policy decisions. More clear and concrete criteria and processes need to be

established by which the regulated entity understands what is required to satisfy this provision. As of today, there are no well-established methodologies that are able to properly assess these types of costs to enable rigorous and meaningful comparisons across all of the A-M elements and all exposure pathways and life cycle segments. The methods are weak, poorly understood and not broadly agreed upon, and may well result in low quality information and extreme controversy across various constituencies. Making decisions based on these methods will not progress the health and well-being of Californians or their environment. **GMA recommends that this aspect of the regulation be deleted.**

#### **§69508 Alternative Analysis Certification**

As previously noted, GMA welcomes the elimination of the Certified Assessor and Accreditation Body concepts.

#### **§69510. Trade Secret Protection.**

Protection for Trade Secrets and Intellectual Property is a core component of this law and is supported by existing California statute and regulations. The proposed regulation includes several aspects that conflict with and/or exceed statutory authority as detailed below.

GMA emphasizes that product formula information in particular is a critical part of a company's trade secrets. The names and concentrations of ingredients in formula will inevitably be claimed secret under this provision to protect investments in innovation. The time-frames for such claims will regularly extend well beyond a few years—such innovations are often core to a product's success for decades. Each innovation can build on and enhance previous innovations and must be protected from disclosure to competitors. It should come as no surprise that substantial portions of AA reports, especially data-based, detailed comparisons of ingredients, economic and technical feasibility and functional acceptability, will be redacted for these reasons and more.

**Chemical Identity.** GMA continues to strongly oppose the provision eliminating protection for chemical identity in connection with the submission of hazard trait information. This is unnecessary and exceeds the department's authority under the statute. Chemical identity should always be claimable as a trade secret. From a legal standpoint, hazard information is distinct from Chemical identity. Traditionally, generic chemical names are provided in connection to the hazard information, which are sufficient for meeting statutory requirements and enabling an appropriate level of public information for the safe use of chemicals. From a policy standpoint, asking companies that have invested millions of dollars on the development of new technologies and products to make them public thus benefitting competitors, is not logical.

The updated proposal allows chemical identity to be claimed as a trade secret if a patent is pending. This shows little understanding of existing commercial practices. Chemical identity is rarely the subject of a patent. A patent is a process that discloses secrets. In particular regarding formulations and manufacturing processes, the vast majority would not be patented, but rather would be protected as trade secrets.

The inclusion of federal law and non-disclosure agreements as criteria for trade secret protection makes sense. However, these exceptions do not ameliorate the overreach of requiring the chemical identity in the first instance. Further, the imposition of these requirements to protect the chemical identity is to modify the statutory definition of a trade

secret. **GMA recommends that the chemical identity always be claimable as a trade secret and that the phrase “...or for any chemical identity information associated with a hazard trait submission” be deleted from 69509(f).**

GMA believes the proposed regulation amount to an unlawful taking by eliminating a Responsible Entity’s ability to consider whether to file for patent protection or retain the information as a trade secret. The proposed regulation punishes Responsible Entities in that it forces a company to file for patent protection thus taking away the option to keep the information as a trade secret. Article 1, Section 19 of the California Constitution provides: “Private property may be taken or damaged for public use only when just compensation, ascertained by a jury unless waived, has first been paid to, or into court for, the owner.” To the same effect, the Just Compensation Clause of the Fifth Amendment of the U.S. Constitution states “... nor shall private property be taken for public use, without just compensation.” Most forms of intellectual property have been recognized and accepted by the Supreme Court as being “property” as protected under these provisions<sup>2</sup>. The Proposed regulations do not provide any compensation for the loss of the ability for a company to protect information as proprietary or trade secrets and therefore it is an unlawful taking by DTSC.

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<sup>2</sup> See, *Ruckelshaus v. Monsanto Co.* 467 U.S. 986 (1984) (the Court recognized that “a trade secret property right is protected by the Taking Clause of the Fifth Amendment.” *Id.* at 1003-04), *Lane v. First Nat'l Bank*, 871 F.2d 166, 174 (1st Cir. 1989) (finding that copyright “taken for public use” gives rise to “a constitutional right to just compensation”); *Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 673 (1999) quoting *Kaiser Aetna v. United States*, 444 U.S. 164, 176 (1979)) (the Court recognized the protection of patents stating that the “hallmark of a protected property interest is the right to exclude others. That is ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property.’”)

# Responses to Peer Review Points

Dale Hattis, Ph.D.

Research Professor, Clark University

February 18, 2013

This document is my peer review of the updated “TEXT OF PROPOSED REGULATIONS – POST-HEARING CHANGES January 2013” for the DTSC regulations (Division 4.5, Title 22, California Code of Regulations). Below I have first provided my specific responses to the four points suggested in the inquiry to me. Then I provide comments on more general issues, and finally there is a section directed to specific parts of the text of the regulations and the statement of reasons document. The peer review points are given in normal type and my responses are provided in bold face.

## Contents

Review Issue 1.....	1
Review Issue 2.....	3
Review Issue 3.....	5
Review Issue 4.....	7
Other Issues Posed by the Current Draft.....	7

The California statute for external scientific peer review (Health and Safety Code section 57004) states that the reviewer’s responsibility is to determine whether the scientific portion of the proposed rule is based upon sound scientific knowledge, methods and practices.

We request that you make this determination for each of the following topics that constitutes the scientific basis of the proposed regulatory action.

Topics:

### Review Issue 1

The use of the chemicals lists developed by the sources named in the regulations identifies chemicals with hazard traits that have public health and environmental concerns to produce an initial Candidate Chemicals

list.

The list of chemicals is now called the “Candidate Chemicals” list. The regulations define “Candidate Chemical” as a chemical that is a candidate for designation as a “Chemical of Concern” (COC). A “Candidate Chemical” that is the basis for a product- chemical combination being listed as a Priority Product is designated as a “Chemical of Concern” with respect to that product. NOTE: This change in terminology does not affect the application of the regulations to the chemicals on the chemicals list.

Revised regulations include the following two additional lists from authoritative organizations to the list of lists for the initial Candidate Chemicals list:

1. Chemicals classified as Category 1 respiratory sensitizers by the European Union in Annex VI to European Commission Regulation 1272/2008.
2. Chemicals identified as priority pollutants in California under the federal Clean Water Act has been expanded to include section 303(d) chemicals in addition to the section 303(c) chemicals.

These lists of chemicals meet the same criteria that were used to identify the sources of chemicals that were in the July proposal. The lists are supported by an authoritative organization, used to limit exposure, and are consistent with similar programs in other states. In all cases, the chemicals on the lists meet criteria as strong evidence for toxicological hazard traits or as evidence for the exposure potential hazard trait in Chapter 54 and the chemical lists are reviewed and updated periodically

**Response: The addition of these two new sources of candidate chemicals seems well founded. They each provide an additional useful perspective on additional chemicals for which there is some basis for concern to the extent they are used in consumer products.**

**This having been said, I have some residual concern with the definition of a “chemical” as used in the strike-through version of the new regulations:**

““Chemical” means either of the following:

1. An organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring, in whole or in part, as a result of a chemical reaction or occurring in nature, and any element, ion or uncombined radical, and any degradate, metabolite, or reaction product of a substance with a particular molecular identity; or
2. A chemical ingredient, which means a substance comprising one or more substances described in subparagraph 1.”

**Some pesticides, (e.g. toxaphene, now eliminated from use) have no single structure but are defined as the product of a chemical reaction (for toxaphene, the reaction of chlorine with camphene, which produces about 200 different individual chemical entities). I think that DTSC will want to be sure that it is clear that such a reaction product based on a mixture with no particular defined chemical structure is covered by the regulations as a “chemical”.**

## **Review Issue 2**

Evaluation criteria for prioritizing the product-chemical combinations in Article 3 are sufficient to identify all types of consumer products containing Candidate Chemicals as potential Priority Products. Revised regulations specify the key prioritization criteria as critical factors necessary to identify potential Priority

Products. The product-chemical combination identified and nominated for Priority Product listing must meet the key prioritization criteria.

The language for the key prioritization criteria have been clarified to illustrate that they must be met for proposing any Priority Product. Also, the phrase “ability to”, as in “The Chemical(s) of Concern in the product have a significant **ability to** contribute to or cause adverse public health and environmental impacts” has been replaced with “potential”: “There must be **potential** public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product.” The revised proposed regulations define “potential” to mean that the

phenomenon described is reasonably foreseeable based on reliable information.

The revised proposed regulations require the Department to evaluate product-chemical combinations to determine potential adverse impacts posed by the Candidate Chemical(s) in the product due to potential exposures which must contribute to or cause significant or widespread adverse impacts.

**Response:** These clarifications are helpful, as far as they go. However there is still much to be defined in determining how DTSC will actually set its priorities in designating particular chemicals with particular hazard traits in particular products. It is clear from the choice to define the priority setting goal in the form of a narrative standard that DTSC does not want to lock itself in to a specific formula. However it seems clear that different formulae will be used for different hazard traits and that in at least in the cases of some hazard traits the formula will look something like:

**Priority score = (potency) X (fraction used in a particular product type expected to reach people [or other type of vulnerable receptor, depending on the hazard trait] X (use volume)**

**In this equation**

- **“potency” can be defined as the reciprocal of the dose found to cause a standardized response (e.g. 1/LD50 for an acutely lethal toxicant in a standard species; 1/ED10 for carcinogenesis over background)**
- **the second term is the “intake fraction” (fraction ingested, inhaled, or otherwise absorbed by people of that used for the purpose)**
- **“use volume” is the annual quantity estimated to be used in a particular product type in California**

**Some variation of this type of scoring is likely to be needed among different hazard traits.**

**It should be emphasized that in an initial analysis, these relative priority scores should be calculated within sets of chemicals expected to exhibit specific hazard traits. Combining the information for different hazard traits is a step that can be left to later analysis. It is also important to understand that the DTSC need not have definitive evidence on the specific numerical values of each of the three components of this equation—the analysts will often need to develop estimates for specific chemicals based on analogies and utilizing adjustments to approximately put somewhat different types of data on comparable scales for ordering.**

**With this kind of elaboration, I think the priority-setting schema can be considered well founded in available risk assessment theory and available data.**

### **Review Issue 3**

The principles outlined in the proposed regulations that will allow the Department to develop Alternatives Analysis Threshold for COCs that are contaminants in Priority Products is scientifically understood and practical

In the revised proposed regulations The Alternatives Analysis Threshold is now defined as the Practical Quantitation Limit (PQL), and the exemption applies only if the Priority Product contains the COC solely as a contaminant chemical. There will not an Alternatives Analysis Threshold provision for an intentionally added ingredient. A list of proposed Priority Products will be subject to California's Administrative Procedures Act (APA) for rulemaking. The APA requires proposals to be made public (public notice) with supporting documentation as to the necessity of the new requirements. Although the revised regulations are silent on this issue, the Department can use the APA rulemaking process in the future to allow for the establishment of an alternative analysis threshold for a product-chemical combination should the need arise.

**Response: Defining the Alternatives Analysis Threshold in this way essentially removes the issue of the degree of hazard posed by analytically detectable amounts of a Chemical of Concern. This is probably reasonable and will cause no great difficulty if the basic formulae for prioritization are well structured and well implemented.**

**Some fairly serious priority-based weaning of candidates for attention is indicated by the new provision in the rules to limit the initial set of product-chemical combinations for attention to five. This is reasonable to focus the efforts of the department. However it does beg the question of how broad the definition of a "product" is. If the definition is as broad as, say, "paint" then it could include hundreds of different formulations made by different companies. Alternatively, is a "product" a specific paint formulation made by a particular manufacturer, perhaps limited to a specific color and place of intended use (e.g. "red indoor residential paint")?**

**In response to an inquiry for clarification, a DTSC worker directed attention to the following passages in the regulations and the “statement of reasons” document:**

“1. Revised Regulations Section 69503.5 (b):

(b) List Contents. The Department shall specify in the proposed and final Priority Products lists the following for each listed product-chemical combination:

(1)(A) A description of the product-chemical combination that is sufficient for a responsible entity to determine whether one or more of its products is a Priority Product.

(B) If the product-chemical combination is a component of one or more assembled products, a description of the known assembled product(s) in which the component is used shall be included.

2. ISOR (keep in mind the ISOR may not entirely line up with the revised regulations)-

[www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf](http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf)

Section 69503.4(a)(2)(B)

DTSC intends to be as specific as possible when products with multiple parts or components are identified as Priority Products to name the specific component or homogeneous material that is basis for the listing, and, thus, subject to the Alternatives Analysis. DTSC may, of course, name an entire multi-component product as a Priority Product when it is appropriate to do so.

3. ISOR-

<http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-ISOR-7-23-2012.pdf>

Section 69503.3(f) specifies that by January 1, 2014, DTSC must issue a Priority Product Work Plan covering next three years.

This is intended to provide a level of certainty and predictability to responsible entities and other stakeholders regarding the types of products that will be considered for evaluation prior to releasing a proposed Priority Product List. The work plan will include product

categories, which may illustrate for example a level of detail comparable to the Family (i.e., Cleaning Products) or Class (i.e., Laundry) hierarchy level identified using the Global Product Classification (GPC) Standards

[<http://www.gsl.org/gdsn/gpc>] and a general explanation, which may include exposure concerns, such as access to sensitive subpopulations. The work plan will plot a course for DTSC for three years.”

**Response continued: Saying that DTSC will be “as specific as possible”, it seems to me, still begs the question of how DTSC will balance the benefits and limitations of defining products relatively broadly or narrowly. A broad definition of a product type will increase the potential benefits of devoting one of the five precious initial chemical-product slots to a particular case. On the other hand the broader the definition of a product, the greater the complexity of the analysis needed to identify reasonably functionally equivalent “alternatives”. The indoor paint example is illustrative. A manufacturer of a specific red pigment might argue that there is no practical alternative to its product if one wishes to achieve a very specific red hue. On the other hand, if one broadens the category to include a wide range of available colors and textures, then many paint formulations and even wallpaper in some cases could be considered as technically feasible alternatives if the “product” were defined as “indoor wall or ceiling covering”. I would suggest that a couple of added paragraphs on this issue could usefully help guide DTSC staff to wiser choices in defining product categories.**

#### **Review Issue 4**

The definitions of the various “adverse” impacts and general usage of the terms “adverse” impacts and “adverse effects” is used throughout the proposed regulations. A qualitative or quantitative determination of adverse impact or effect can be made, and is adequately protective of public health and the environment when reliable information is available.

Minor clarifications were made to these terms, including, in some instances, changing “impact” to “effect”, where appropriate.

**Response: These minor clarifications do not seem to pose significant problems.**

#### **Other Issues Posed by the Current Draft**

**(Page numbers refer to the 106 page revised text of the regulations with strikeouts and additions).**

**\*P 12 ,line 22-- (29) “Economically feasible” means that an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.**

**Without further elaboration of what is meant by “significantly” this provision might be used to argue infeasibility for changes that decrease the manufacturer’s operating**

margin by 1-5%. This should be specified more clearly lest extensive litigation result.

“Functionally acceptable” means that an alternative product meets both of the following requirements:

(A) The product complies with all applicable legal requirements; and

(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

This definition seems good to me.

p. 13-- “Importer” means a person who imports a consumer product into the United States product that is subject to the requirements of this chapter. “Importer” does not include a person that imports a product solely for use in that person’s workplace if that product is not sold or distributed by that person to others.

**I am concerned that the last sentence in this definition could cause problems. Imagine that a maker of plywood or particle board imports an adhesive known to contain and emit formaldehyde. If “the product” is the adhesive, then the importer could argue that he just used the adhesive in his workplace to make the plywood or particle board but did not sell or distribute the adhesive itself. This would allow such a person/firm perhaps to get around the fact that consumers could be extensively exposed to emissions from the plywood or particle board manufactured with the adhesive. This, it seems to me, should be a prime candidate for regulation by DTSC, but may escape regulation unless the language is changed to make it clear that a product (e.g. plywood or particle board) that incorporates the imported material that causes such emissions and consumer exposures is subject to controls.**

p. 65, line 1—“ (C) Economic impacts.

1. The responsible entity shall evaluate, monetize, and compare for the relevant exposure pathways and life cycle segments the following impacts of the Priority Product and the alternatives:

a. Public health and environmental costs; and

b. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.”

**The suggestion that alternatives analyses include monetization of impacts might be qualified by some caveat like (where reasonably feasible) or some such. This is to avoid hanging up the process in very difficult issues such as how much a fish in the wild is worth, or how much an uncertain mild health response is worth.**

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February 25, 2013

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**RE: COMMENTS ON SAFER CONSUMER PRODUCT PROPOSED REGULATIONS**

Dear Director Raphael:

Thank you for the opportunity to review and comment on the California Department of Toxic Substances Control's (Department or DTSC) January 2013 proposed Safer Consumer Products (SCP) regulations (Proposed Regulations).

Hewlett-Packard (HP) strongly supports the removal of the certified assessor requirements and all provisions relating to assessors and accreditation bodies. We also support the modifications that allow the selection of more than one alternative during the Alternative Assessment (AA) process, as well as the many clarifications and improvements throughout the Proposed Regulations.

HP has provided additional comments in support of specific changes made in the Proposed Regulations in the attachments.

However, there are still critical areas in need of adjustment in the Proposed Regulations. HP recommends the following and describes each in more detail below:

- Revise the AA Requirements to Focus on the Most Important Factors, and Enable the Use of Standard Environmental Analysis Tools in Both Stages
- Develop a Single Regulatory Response per Product-Chemical Combination
- Revise the Alternative Analysis Threshold (AAT) with Respect to Practical Quantitation Limit (PQL)
- Harmonize Substantiation Questions to Keep Company Information Confidential with Information Necessary to Satisfy Trade Secret Status under California's Uniform Trade Secrets Act

We have also prepared tables of additional comments to the Proposed Regulations that are in the Attachments 1 through 7.

**James Wilie**

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## DTSC Should Revise the AA Requirements to Focus on the Most Important Factors and Enable the Use of Standard Environmental Analysis Tools in Both Stages

HP recommends the following:

- Focus the Stage 1 analysis on relevant factors and clarify that Stage 1 can be satisfied by applying standard tools and methods, even if the complete list of 80 impact area may not be explicitly addressed.<sup>1</sup>
  - If the Department is not comfortable letting entities choose their own tools and methods (out of concern that important criteria could be overlooked), DTSC could publish a minimum set of required impact areas at the time of listing the product-chemical combinations to ensure that areas of concern are specifically addressed. As an alternative, the Department could make a list of Stage 1 approved tools available in the guidance documents.
  - To add another measure of caution, Stage 1 could require, at a minimum, that the replacements show reduced impacts in the specific areas that caused the Chemical of Concern (CoC) to be listed.

### Proposed text:

§ 69505.5. (c) Step 3, Initial Evaluation and Screening of Alternative Replacement Chemicals.

(1) For those alternatives under consideration that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, or otherwise adding chemicals to the product, the responsible entity shall:

(A) Identify relevant factors for screening of replacement chemicals. A factor is relevant if it makes a material contribution in any life cycle segment to one or more:

1. Adverse environmental impacts;
2. Adverse public health impacts;
3. Adverse impacts associated with environmental fate, physical chemical hazards, or physicochemical properties.

The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors.

(B) Compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product, using the relevant factors identified in subparagraph (A) as the minimum set of impact areas.

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<sup>1</sup> This approach is consistent with the goal of the first stage from the Initial Statement of Reasons (ISOR): *The principal goal of the first stage [...] is to identify all potential alternatives to the Priority Product, and eliminate those alternatives that pose greater aggregate or cumulative public health and environmental impacts than the Chemical of Concern.*

(C) Evaluation and comparisons of alternative replacement chemicals may be accomplished with any tool, approach, or method chosen by the responsible entity, as long as all relevant factors identified in subsection (A) are addressed. Information describing the tool, method, or approach must be included in the Preliminary AA Report.

(2) The responsible entity must eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines does not reduce the adverse impacts in the areas that caused the original Chemical(s) of Concern to be listed.

(3) The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern.

- Modify Stage 2 to focus on life cycle issues, including material and resource consumption impacts and waste and end-of life impacts, and relevant impact areas from Stage 1 that may involve trade-offs or require more detailed analyses. Economic analysis requirements should be scaled to the level of risk, depending on the intended replacement of the CoC.<sup>2</sup>
  - By focusing on the resource consumption and waste impacts, standard life cycle analysis (LCA)-based approaches open up as a possibility for completing the Stage 2 analysis.
  - Also, by narrowing the human health and environmental impacts to the relevant ones identified in Stage 1, in depth analysis methods, such as risk assessment or Multiple Criteria Decision Analysis (MCDA), can be used. If Stage 1 is done well, there should be no need to repeat the analyses in Stage 2.
  - Importantly, the economic analysis requirements should be tiered such that eliminating the CoC and replacing it with a non-Candidate Chemical requires no economic analysis, while retaining the CoC or replacing it with a Candidate Chemical requires a more complete economic analysis, including consideration of externalized costs. Externalized costs are extraordinarily difficult to calculate, and responsible entities should not be penalized with such an analysis when they are proposing to phase out a CoC.
  - The product function section can be simplified because performance and legal requirements have already been determined in Stage 1.

Proposed text:

§ 69505.6. Alternatives Analysis: Second Stage.

After receiving approval of the Preliminary AA Report from the Department, the responsible entity shall compare the Priority Product with the alternatives still under

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<sup>2</sup> This approach is consistent with the goal of the second stage in the ISOR:

*The principal goal of the second stage [...] is to further evaluate the alternatives identified in the first stage.*

consideration. The second stage of the AA shall include the five (5) steps described below:

(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.

(1) A factor is relevant if:

(A) The factor makes a material contribution to materials and resource consumption and/or adverse waste and end-of-life effects associated with the Priority Product and/or one or more alternatives under consideration; or

(B) The factor has been identified as relevant from Stage 1 and:

1. There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or

between two or more alternatives; and

2. There is an associated exposure pathway, if applicable. The responsible entity's identification of relevant exposure pathways shall consider both of the following:

a. Chemical quantity information:

1. Quantities of the Chemical(s) of Concern or replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and

2. Estimated volume and/or mass of the Chemical(s) of Concern or replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.

b. Exposure factors specified in section 69503.3(b).

(2) The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information, to identify the factors specified in paragraph (1)(A).

(3) The factors identified in subparagraphs (A) and (B) are relevant for all comparisons of the Priority Product and the alternatives.

(A) Product function and performance. The responsible entity shall, at a minimum, evaluate:

1. The useful life of the Priority Product, and that of the alternatives under consideration;

2. The function and performance of each alternative relative to the Priority Product and other alternatives under consideration using the functional, performance, and legal requirements identified in 69505.5 (a)(1); and

3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.

(B) Economic impacts.

1. If none of the replacement chemicals under consideration are Candidate Chemicals or Chemical(s) of Concern, no economic analysis is required.

2. If any replacement chemical under consideration is a Candidate Chemical, or if the Priority Product with the Chemical(s) of Concern is to be retained, the responsible entity shall evaluate, monetize, and compare the following impacts of the Priority Product and the alternatives:

a. Quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs;

- b. Public health and environmental costs; and
- c. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

## Discussion

HP is extremely concerned that there is too much analysis required for both stages of the AAs. Additionally, there are duplications in Stage 1 and Stage 2 that must be eliminated.

The expanded list of factors required for the First Stage AA (§69505.5) contains 80 impact areas and 130 named substances (within impact areas) for consideration. See Attachment 8. Although Stage 1 does not require explicit consideration of each life cycle segment, it unfortunately also does not allow for narrowing the scope of the evaluation based on importance or relevance (as in Stage 2).

*§69505.5(c)(1)(A) "...use available information on hazard traits and environmental and toxicological endpoints and any other relevant information to identify the following for each alternative replacement chemical under consideration." [emphasis added]*

There are tools available for evaluating some of the 80 factors, but no standard tool addresses all of them. To ensure that each impact area is addressed, manual, unique assessment approaches will be needed.

The expanded list of factors for the Second Stage AA (§69505.6) is larger with 86 impact areas across 12 life cycle segments (§69501.1(a)(42)) for a total of 1,032 combinations. The 86 impact areas include re-analyzing the 80 topics from Stage 1 (including the 130 individual chemicals) plus 6 additional areas from two large topics such as waste and materials consumption (including energy and greenhouse gas).

Stage 2 allows a narrowing of scope by requiring only "relevant" factors to be considered. There is a four-part criteria for relevance. A factor is relevant if it has:

- 1) An associated exposure pathway (if applicable) within a
- 2) Life cycle segment (if applicable); and
- 3) Makes a material contribution to one or more adverse public health impacts, adverse environmental impacts, adverse waste and end-of-life effects, and/or materials and resource consumption impacts associated with the Priority Product and/or one or more alternatives under consideration; and
- 4) There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives.

Even with this narrowing, the Second Stage still requires a large amount of analysis. Additionally, if relevance must be determined independently for each potential alternative (because there might be impacts in different life cycle segments for different alternatives), the number of potential combinations that must be addressed could reach hundreds of individual analyses if several alternatives are considered.

The argument for setting an expansive scope in the Proposed Regulations is that the historic narrowing of scope that expert practitioners rely on is actually a source of some of the unintended consequences on public health and the environment. By setting the goals and scope of the assessments uniformly and comprehensively, the hope is that assessments will yield a more complete picture of the human health and environmental impacts of chemicals and their potential alternatives.

It is an admirable goal, yet implementing such an approach is not as straightforward as it seems.

Environmental decisions can be very complicated, require multiple disciplines, and are often based on data with some level of uncertainty. An impressive number of individuals and groups have grappled with the question of what constitutes a good environmental decision and how to make one. There are a plethora of models, tools, and frameworks to help decision makers. Interestingly, all approaches share one important feature: they do not attempt to include every possible factor in their analyses.

So why do we not consider every possible impact when we make environmental decisions?

There are two answers: 1) resources are limited in the real world, so even the most diligent decision makers cannot support the nearly infinite number of factors that could be invoked to make a single decision; and 2) including more factors in an analysis does not necessarily lead to more predictive models. If the point of an analysis is to predict the likely outcomes of different choices to inform decision making, then the model need only include as many elements as necessary to describe the system but no more.

The latter point is often referred to as parsimony. A common statement of parsimony is Occam's Razor which suggests explaining phenomena by the simplest hypothesis possible ("plurality should not be posited without necessity"). The reason the ideal of parsimony endures is that simple models can often be more predictive (and more useful) than excessively complex ones, especially in cases where there is considerable noise or uncertainty in the data, a situation not uncommon in environmental decision making.

Although the expansive list of factors for the First and Second Stage AAs are intended to yield a more predictive model of the human health and environmental impacts of

chemicals and their potential alternatives, considering every possible factor will not necessarily lead to more predictive models, and therefore will not lead to better decisions or outcomes. Since an abundance of factors does not assure a better decision, the task of evaluating alternatives to CoCs can reasonably be accomplished using well-constructed, structured tools and methods developed and peer-reviewed by environmental specialists and consisting of a narrower list of factors that are relevant or that can serve as useful proxies for phenomena.

Finally, requiring a level of analysis that cannot reasonably be accomplished by the regulated community, such as the approach described in Article 5, threatens the successful implementation of this important and valuable new class of regulation that seeks to ensure that replacements for CoCs are properly evaluated. HP recommends that the requirements for the First and Second Stage AAs be adjusted to better fit the capabilities of the entities and environmental scientists who will be tasked to carry out the work, in ways that will not substantially degrade the quality of the information, decisions, or outcomes.

### **DTSC Should Develop a Single Regulatory Response per Product-Chemical Combination**

HP recommends the following:

- Explicitly require DTSC to issue a single regulatory response for each chemical-product combination, based on the aggregate finding of all AAs where multiple AAs are submitted.
- Where multiple AAs are submitted, state clearly that the deadline for submission of AA Reports will be the same for all responsible entities and that any extension granted for one responsible entity will apply for all responsible entities.

### **Discussion**

AB 1879 provides that DTSC shall adopt regulations “to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern” after establishing a process for evaluating chemicals of concern in consumer products and their potential alternatives. Health and Safety Code §25253(a)(1). In the Proposed Regulations, DTSC states that it shall “seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.” §69506(a). DTSC further states that when selecting regulatory responses, DTSC “shall give preference to regulatory responses providing the greatest level of inherent protection.” §69506(b).

At the onset, limiting exposure and reducing the level of hazard is a far different standard than maximizing the use of alternatives of least concern and providing the greatest level of inherent protection. HP encourages DTSC to review and revise the Proposed Regulations to ensure that the standard for determining regulatory responses meets the standard required by AB 1879.

If DTSC maintains the standard for determining regulatory responses as currently proposed -- and DTSC intends to select regulatory responses that “maximize the use of alternatives of least concern” and that provide “the greatest level of inherent protection” -- it follows that DTSC should select the same regulatory responses for every responsible entity that submits an AA for a particular chemical-product combination.

If DTSC imposes various regulatory responses for different companies for the same chemical-product combination, it can be challenged that it has not “maximized” the use of alternatives of least concern or provided the “greatest” level of inherent protection, and it can be challenged that it has treated companies unfairly by demanding one set of regulatory responses for one entity when another set of regulatory responses also met the statutory standard. This situation will create public confusion and misunderstandings if consumers are unable to determine why the same product made by different manufacturers has different, potentially conflicting notices about the composition, use, controls, end-of-life management, etc. of that product.

Moreover, non-uniform regulatory responses could have a chilling effect on companies wanting to do business in California if the same product can be formulated differently elsewhere or if certain companies are subject to more stringent regulatory responses than others. Companies and consumers will question how DTSC made such seemingly arbitrary determinations and what preferences it may have given certain companies. DTSC should avoid even the appearance of arbitrariness and impropriety when making such decisions.

The result of the Proposed Regulations as currently written is to create the potential for dramatically disparate treatment of similarly situated responsible entities by allowing different, potentially inconsistent regulatory responses for different responsible entities submitting individual AAs for the same chemical-product combination. It is understood that responsible entities may propose different regulatory responses when preparing separate AAs, but developing a single regulatory response per chemical-product combination following a review of all relevant AAs will allow DTSC to determine those regulatory responses that both meet the statutory standard and can be applicable across that industry.

If DTSC is able to identify multiple alternative chemicals of lower concern and regulatory responses that would satisfy its standard, then those alternatives should be available to all similarly affected responsible entities. This approach would be consistent with how agencies regulate chemical substances and/or products around the globe (*e.g.*, Registration, Evaluation, Authorization and Restriction of Chemical Substances (REACH) authorizations/restrictions, Toxic Substances Control Act (TSCA) significant new use rules (SNUR), Consumer Product Safety Commission (CPSC) regulated products) by providing uniform restrictions and requirements for responsible entities.

DTSC would have no authority to disclose information claimed as trade secrets when informing responsible entities of the selected regulatory responses, but that constraint does not alter DTSC's responsibility to select the regulatory responses that meet its criteria and ensure that no company is permitted to proceed under a regulatory response that is less "safe" than what is selected for other entities (with the understanding that the only deviation from a uniform regulatory response may be the need to provide the product sales prohibition notification described in §69506.5). To do otherwise arguably benefits those companies that put less effort and resources to find "safer" alternatives and reformulations.

A related corollary to selecting a single regulatory response per chemical-product combination is HP's suggestion that DTSC ensure that all deadlines and extensions for submission of AA Reports are the same for all related responsible entities. The Proposed Regulations should state clearly that all AA Reports will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all. Just as the Department extends a comment period for all persons based on the extension request of one, so too should the Department ensure that all AA Reports are submitted simultaneously to ensure that entities are treated fairly in having the same amount of time to prepare AAs. Equally important, entities should not be disadvantaged by the Department reviewing AAs successively and issuing regulatory response determinations at different times.

If these changes are not implemented, DTSC could be creating an uneven playing field that will disadvantage responsible entities that submit timely and thorough AAs. This could be the case, for example, if DTSC reviews timely submitted AAs and sets forth regulatory response decisions in a proposed notice of determination in the time required (*i.e.*, ninety (90) days after the Department issues the notice of compliance or notice of disapproval) before other AAs for the same chemical-product combination are even submitted. This unintended consequence should be avoided.

### **DTSC Should Revise Alternative Analysis Threshold (AAT) Definition and Scope**

HP recommends the following:

- Add §69503.5(b)(4) a list of acceptable analytical methods and their PQLs for the CoC in components below which no AA must be completed.
- Delete §69505.3(a)(5).

### **Discussion**

The AAT has been defined in relation to the Practical Quantitation Limit (PQL), but a PQL is only meaningful with respect to a particular analytical method. In the Proposed Regulations, responsible entities are to select an appropriate analytical method to determine if the level of a CoC falls below a threshold that requires an AA (§69505.3.(a)(5)), essentially determining their own AATs by the choice of analytical method, leading to potential inconsistency between entities.

For consistency, DTSC should select acceptable analytical methods, matrices, and PQLs for the relevant CoC(s) and include this information in the Priority Product-CoC listing.

### **DTSC Should Harmonize Substantiation Questions to Keep Company Information Confidential with Information Necessary to Satisfy Trade Secret Status under California's Uniform Trade Secrets Act**

HP recommends the following:

- Revise substantiation questions to only seek information necessary to establish trade secret status under California's Uniform Trade Secrets Act (Civil Code Sections 3426.1- 3426.11).
- Extend the time for responsible entities to respond to notifications regarding trade secret substantiation to ninety (90) days.

### **Discussion**

HP urges DTSC to ensure that its substantiation requirements focus on information necessary to meet the criteria for "trade secret." "Trade Secret" under the Proposed Regulations is defined as the same definition under California Civil Code Section 3426.1(d). California Civil Code Section 3426.1(d) defines trade secret as "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."

Not all of the substantiation questions in the Proposed Regulations seek information necessary to establish information as trade secret. Sections 69509(a)(6) and (a)(7), for example, ask for an explanation of the "estimated value of the information to the person and the person's competitors" and the "estimated amount of effort and/or money expended by the person in developing the information."

Since the standard for claiming information as trade secret includes information that "derives independent economic value, actual or potential," the Proposed Regulations should likewise make clear that the Department is not necessarily seeking specific economic values but rather actual or potential economic value.

A specific cost estimate could be a potentially enormous undertaking considering all of the R&D, product testing, market development, technical support, and other related activities involved. We encourage DTSC to ensure it is not requiring any unique or burdensome substantiation that could not be compiled in a timely fashion and that companies are not currently required to collect and maintain under the trade secret analysis of California Civil Code Sections 3426.1- 3426.11.

February 25, 2013

Finally, the substantiation required in this draft will require a significant amount of time to collect or document and any company provided notice that its substantiation does not meet the criteria must be provided sufficient time to respond under §69509.1. Thirty (30) days is simply too short a timeframe to allow a company to compile additional information or otherwise defend itself. There will be no substantive harm to DTSC if it affords companies more time to respond but there could be substantive, permanent harm if DTSC discloses trade secret information merely because a company did not have sufficient time to respond.

HP appreciates the opportunity to comment on the Proposed Regulations and looks forward to continuing our work with the Department in creating a balanced regulation that meets the goals of AB 1879.

Regards,

A handwritten signature in cursive script that reads "James Wilie".

James Wilie  
Hewlett-Packard  
Environmental Compliance Program Manager

Cc: Jennifer Morris, HP  
Helen Holder, HP  
Barbara Hanley, HP  
Jon Dickinson, HP

Attachments

**ATTACHMENT 1  
ARTICLE 1**

<b>Article 1 - General</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
		The Proposed Regulations are not consistent in capitalizing throughout the text the terms that have been defined in Article 1. The Department should review and revise the Proposed Regulations as necessary so it is clear when it is referring to a defined term.	
<i>Previously § 69501.1(a)(2)</i>	Accreditation Body	HP strongly supports DTSC's decision to eliminate the accreditation bodies program.	
§ 69501.1 (a)(2)	Adverse air quality impacts	HP supports DTSC's clarification of adverse air quality impacts to include indoor and outdoor air emissions.	
§ 69501.1(a)(12)	Alternatives Analysis Threshold	HP does not believe that the revised definition is acceptable. A Practical Quantitation Limit (PQL) is meaningless if there is no reference to an analytical method. DTSC could clarify this issue by stating that acceptable analytical standards for a PQL will be published by DTSC at the time of a Priority Product listing for a Chemical of Concern that is present in a Priority Product solely as a contaminant.	"Alternatives Analysis Threshold" means the Practical Quantitation Limit <b>(based on analytical methods, matrices, and standard(s) to be published by the Department)</b> for a Chemical of Concern that is present in a Priority Product solely as a contaminant.
<i>Previously § 69501.1(a)(18)</i>	Certified Assessor	HP strongly supports DTSC's decision to eliminate the certified assessor program.	
§ 69501.1(a)(19)	Candidate Chemical	HP supports DTSC's addition of the term "candidate chemical" that recognizes the difference between the extended list of "candidate" chemicals and the specific "Chemicals of Concern" that are identified in a listing with a Priority Product.	
§ 69501.1(a)(23)	Component	HP finds the reorganized definition of component helpful and supports the decision to retain the ability to specify homogenous material, if appropriate.	
§ 69501.1 (a)(26)	Contaminant	HP disagrees with DTSC's proposal to limit the alternative assessment threshold to contaminants. HP does not believe it matters whether a Chemical of Concern is intentionally added or not. It should only matter whether it is present. HP believes this definition (and all related definitions) should be eliminated and Section 69505.3(a)(4) should be adjusted to only focus on whether the substance is present or not. The risk of having a Chemical of Concern as a low level contaminant can still be addressed as part of an Alternative Assessment.	Delete the definition in its entirety.
§ 69501.1(a)(51)	Potential	HP understands the need to consider reasonable foreseeable impacts and exposures and thus supports DTSC's re-introduction of the term "potential" in this definition and throughout the Regulations so that the range of chemical-product combinations can be broadened and DTSC can consider cases beyond those with demonstrated harm.	
§ 69501.1(a)(52)	Practical Quantitation Limit	As HP's noted above ( <i>see</i> Section 69501.1(a)(12)) the definition of PQL is meaningless if there is no reference to an analytical method. DTSC should clarify this issue by stating that PQLs for the accepted test methods will be published by DTSC.	"Practical Quantitation Limit" or "PQL" means the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures, <b>as published by DTSC with accepted analytical method(s).</b>

**ATTACHMENT 1**  
**ARTICLE 1**

<b>Article 1 - General</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69501.1(a)(59)	Replacement Candidate Chemical	HP suggests clarifying the second part of the definition to: "A chemical that is present in the original listed Priority Product, the concentration of which may be adjusted in an alternative to the Priority Product to eliminate or reduce the concentration of the Chemical(s) of Concern."	"Replacement Candidate Chemical" or "replacement chemical" means a Candidate Chemical or other chemical, whichever is applicable, that replaces, or is under consideration to replace, the Chemical(s) of Concern, in whole or in part, in an alternative to the Priority Product, and that is one of the following: (A) A chemical that is not present in the Priority Product; or (B) A chemical that is present in the original listed Priority Product, the concentration of which may be adjusted in an alternative to the Priority Product.
§ 69501.2(a)	Duty to Comply	HP finds the clarifications as to who is responsible for submitting notifications helpful.	
§ 69501.5(a)(5)	Due date extensions for AA Reports	HP supports DTSC's proposal to list the due date extensions for AA Reports on its website, but continues to object to the unfair decision by DTSC to allow different deadlines and extensions for different responsible entities submitting AAs for the same chemical-product combination. When DTSC or any regulatory agency extends a comment period, it is applicable to all submitters, not just the entity seeking the extension.	A list of due date extension requests approved for submission of <b>all</b> AA Reports <b>for that particular chemical-product combination</b> .
§ 69501.5(a)(6)	AA report notice of public review period	HP understands DTSC's decision to allow a public review and comment period for Preliminary AAs, draft Abridged AA Report, and Alternate Process AA Work Plan as a means to provide a quality assurance mechanism now that the certified assessor and accreditation bodies provisions have been eliminated. DTSC must develop a clear mechanism for the submission of comments and provide additional guidance on the requirements for entities to respond to public comments. See also §§ 69505.1. (d)(2), 69505.7(i)(1).	

**ATTACHMENT 2  
ARTICLE 2**

Article 2 -- Process for Identifying Candidate Chemicals			
Section	Title	Comment	Proposed Text
§ 69502.2.(a)	Candidate Chemicals List	HP continues its support of DTSC generating a Candidate Chemicals list that relies on appropriate authoritative bodies that will be harmonized with other jurisdictions. If the sources from which DTSC derives its Candidate Chemicals list are not from authoritative bodies that are properly maintained, however, the integrity of the Candidate Chemical List will be compromised.	
§ 69502.2.(a)(1)(l)	Respiratory Sensitizers	HP supports the addition of chemicals classified as respiratory sensitizers Category 1 in Annex VI to Regulation (European Commission) 1272/2008.	
§ 69502.2.(a)(1)(H)	CA DSL PBIT list	HP renews its objection to the inclusion of the CEPA PBIT list referenced in 69502.2 (a)(1)(H)) because it is not an authoritative list and will not be maintained over time. It was a very useful screening step but it provided only a one-time review of substances on Canada's DSL. The more appropriate authoritative list would be Schedule 1. Schedule 1 is maintained over time, is based on expert review, has been prioritized, and covers both existing and new substances used in commerce.	69502.2 (a)(1)(H)) Chemicals that are identified as <del>Persistent, Bioaccumulative, and Inherently Toxic Substances to the environment by</del> in the Canadian Environmental Protection Act Environmental Registry <del>Domestic Substances List</del> <b>Schedule 1.</b>
<i>Previously § 69502.2.(b)(4)</i>	Safer Alternative	HP supports DTSC's decision to deleting the prior Section 69502.2(b)(4) because the existence or not of a "safer alternative" should have no bearing on whether a chemical is identified as a Candidate Chemical.	

**ATTACHMENT 3  
ARTICLE 3**

<b>Article 3 -- Process for Identifying and Prioritizing Product-Chemical Combinations</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69503.2. (a)	Key Prioritization Principles	HP supports the reorganization and simplification of this section by moving the key prioritization factors to the beginning. There is still some concern that the Regulations are not following the statutory requirements in AB 1879 ( <i>i.e.</i> , consider volume of the chemical in commerce, the potential for exposure in a consumer product, and potential effects on sensitive subpopulations) before weighing other prioritization factors.	
§ 69503.2. (b)	Identification and Prioritization Factors	HP supports the changes that now allow at this stage the appropriate consideration of existing safer alternatives.	
§ 69503.2. (b) (1)(A)	Adverse Impacts and Exposures	DTSC should clarify whether its prioritization process will start by reviewing the chemical or the product when evaluating exposures as described in Section 69503.2(b).	
§ 69503.2. (b)(2)	Other Regulatory Programs	HP supports the revisions regarding the Department's consideration of other regulatory programs.	
§ 69503.3. (b)(1)(F)	Containment of the Candidate Chemicals	HP supports the revisions DTSC proposes to this factor to consider whether a substance will be accessible during use or at end of life.	
§ 69503.5. (a)(2)	Administrative Procedure Act	HP supports DTSC's revision to specify that the Priority Products list will be established and updated through rulemaking pursuant to the Administrative Procedure Act.	
§ 69503.5. (b)	List Contents	HP is concerned that the Priority Products list does not include a statement of the PQL and preferred analytical test method(s) if the Chemical of Concern may be present as a contaminant.	<b>(4) The analytical method, matrices, and standard(s) to be used to determine a PQL for a Chemical of Concern.</b>
§ 69503.5. (b)(2)(A)	Listing Criteria	HP supports the clarification that the Priority Product list will include a description of the hazard traits and/or environmental or toxicological endpoints associated with those chemicals. HP believes this Priority Product list contents could additionally include information about the criteria and/or potential acceptability of any alternatives.	
§ 69503.5. (e)	Priority Product Notifications	It appears to HP that there is a duplication of Priority Product notifications between Section 69503.5(e) and 69503.7. DTSC must delete duplicative requirements or otherwise clarify in the Regulations what the difference is between these two Sections.	
§ 69503.6. (d)(2)	Workshops	HP does not understand why DTSC would not hold one or more public workshops prior to issuing the initial list of Priority Products. HP believes all entities, including DTSC, would benefit greatly from a workshop for the initial list. In fact, the initial list will provide a great deal of information regarding how the prioritization and selection process will occur and will provide important information to all stakeholders trying to anticipate what other Priority Products may be listed.	<del>(2) Workshops. The provisions of section 69503.5(a)(2) requiring the Department to hold one or more public workshop(s) prior to issuing the proposed Priority Products list do not apply to the initial list of Priority Products.</del>

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.1. (b)(2)(B)	AA Requirements	As noted throughout these comments, DTSC must state clearly that all AA Reports will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all. Just as the Department extends a comment period for all persons based on the extension request of one, so too must the Department ensure that all AA Reports are submitted simultaneously to ensure that entities are treated fairly in having the same amount of time to prepare AA Reports. Equally importantly, entities must not be disadvantaged by the Department reviewing AA Reports successively and making regulatory response determinations.	(B) Except as provided in subsection (c), a responsible entity shall submit the Final AA Report no later than twelve (12) months after the date the Department issues a notice of compliance for the Preliminary AA Report, unless <del>the responsible entity requests, and</del> the Department approves an extended due date <b>applicable to all responsible entities for a particular chemical-product combination.</b>
§ 69505.1. (c)(3)	AA Report Due Date Extension	As noted throughout these comments, DTSC must state clearly that all AA Reports will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all.	The Department shall approve or deny the extension request in whole or in part and provide notice to the person submitting the extension request of the decision, within thirty (30) days of receipt of the extension request. <b>If the Department grants an extension, it shall send to individuals on the electronic mailing list(s) that the Department establishes related to this chapter, and post on its website, a notice of the extension and the new due date.</b> Failure by the Department to issue a decision within thirty (30) days does not constitute an approval of the extension request.
§ 69505.1. (d)(2)	Public Comments on Stage 1 AA	HP understands DTSC's decision to allow a public review and comment period for Preliminary AAs, draft Abridged AA Report, and Alternate Process AA Work Plan as a means to provide a quality assurance mechanism now that the certified assessor and accreditation bodies provisions have been eliminated. DTSC must develop a clear mechanism for the submission of comments and provide additional guidance on the requirements for entities to respond to public comments so it is clear that specific responses to each submitted comment is not required. DTSC also should clarify that the Reports posted on the website will be the versions with masked trade secrets as provided under Section 69505.7(a)(4). See also §§ 69501.5. (a)(6), 69505.7(i)(1).	The Department shall post on its website a notice regarding the availability for public review and comment of each Preliminary AA Report, draft Abridged AA Report, and Alternate Process AA Work Plan submitted to the Department <b>and for which claimed trade secret information has been masked.</b>
§ 69505.2. (a)	Applicability	HP supports the procedures under which responsible entities would be allowed to avoid AA requirements in circumstances when a COC is removed, a product is removed, or there is a product-chemical replacement.	
§ 69505.2. (b)(4)	Content Requirements for Intent and Confirmation Notifications	As part of a notification in lieu of the requirement to conduct an AA, DTSC is asking for extensive information on customers and distributors that is likely to be considered commercially sensitive and confidential information. Instead of requiring this information in all notifications, which will be burdensome for the Department to manage and of little upfront utility, DTSC should seek such information when it is conducting audits under Section 69508. DTSC has the authority under Section 69508 to examine compliance with Article 5 requirements, including but not limited to information related to notifications. DTSC could specify in Section 69508 that it can seek the customer and distributor information currently sought in this Section although HP does not believe it necessary to specifically list this when its broad authority is already established. It should also be noted that the Regulations also require under Section 69505.7(k)(2) that responsible entities provide with the Final AA Report an implementation plan with steps to be taken to ensure compliance, which will allow the Department to understand how the selected alternatives will be implemented without the need for particular customer information.	

ATTACHMENT 4  
ARTICLE 5

Article 5 -- Alternatives Analysis			
Section	Title	Comment	Proposed Text
§ 69505.2. (b)(9)(D)	Name of replacement chemical	HP supports the requirement to provide information on the COC being removed or the name of the replacement chemical and its concentration in the reformulated product. This type of information is necessary upfront for DTSC to ensure that the removal or reformulation does not increase potential exposures or adverse impacts, in contrast to customer and distributor lists that, as discussed above, are not necessary for DTSC to make an upfront determination that the criteria for a notification have been satisfied.	
§ 69505.2. (b)(9)(F)(1); § 69505.2. (e)(2)(B)	Information About Replacement Chemical	HP supports the requirement to provide information showing that criteria for a replacement chemical are met. This type of information is necessary upfront for DTSC to ensure that reformulation does not increase potential exposures or adverse impacts, in contrast to customer and distributor lists that, as discussed above, are not necessary for DTSC to make an upfront determination that the criteria for a notification have been satisfied.	
§ 69505.2. (c)(1)(B)	Notifications to distributors (Chemical Removal Intent)	DTSC should clarify how responsible entities must notify persons selling or distributing the Priority Product in California regarding the reformulated product by specifying that posting information on a company website is sufficient notice.	Provide information, <b>including but not limited to notification on a responsible entity's website</b> , regarding the reformulated product to persons selling or distributing the Priority Product in California
§ 69505.2. (c)(2)(B)	Notifications to distributors (Chemical Removal Confirmation)	DTSC should clarify how responsible entities must notify persons selling or distributing the Priority Product in California regarding the reformulated product by specifying that posting information on a company website is sufficient notice.	Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California, <b>including but not limited to notification on a responsible entity's website</b> .
§ 69505.2. (e)(1)(B)	Notifications to distributors (Chemical Removal Intent)	DTSC should clarify how responsible entities must notify persons selling or distributing the Priority Product in California regarding the reformulated product by specifying that posting information on a company website is sufficient notice.	Provide information, <b>including but not limited to notification on a responsible entity's website</b> , regarding the reformulated product to persons selling or distributing the Priority Product in California
§ 69505.2. (e)(2)(C)	Notifications to distributors (Chemical Removal Confirmation)	DTSC should clarify how responsible entities must notify persons selling or distributing the Priority Product in California regarding the reformulated product by specifying that posting information on a company website is sufficient notice.	Information regarding the reformulated product has been provided to persons selling or distributing the Priority Product in California, <b>including but not limited to notification on a responsible entity's website</b> .
§ 69505.3. (a)(4)	Contaminant	HP disagrees with DTSC's proposal to limit the alternative assessment threshold to contaminants. HP does not believe it matters whether a Chemical of Concern is intentionally added or not. It should only matter whether it is present. HP believes the definition at Section 69501.1 (a)(26) should be eliminated and Section 69505.3(a)(4) should be adjusted to only focus on whether the substance is present or not. The risk of having a Chemical of Concern as a low level contaminant can still be addressed as part of an Alternative Assessment.	A statement certifying that the Chemical(s) of Concern are present in the manufacturer's Priority Product only as contaminants and the at a concentration of each Chemical of Concern does not exceed the Alternatives Analysis Threshold for that chemical;
§ 69505.3. (a)(5)	PQL and Analytical Method	A Practical Quantitation Limit (PQL) is meaningless if there is no reference to an analytical method. DTSC could clarify this issue by stating that acceptable analytical standards for a PQL will be published by DTSC at the time of a Priority Product listing for a Chemical of Concern that is present in a Priority Product solely as a contaminant.	Identification of the PQL for each Chemical of Concern in the Priority Product, <del>and the information</del> <b>and based on the analytical method(s) published by DTSC to be used to determine the PQL;</b>
§ 69505.3. (a)(5)	Representative product testing	It is common for different products from the same company to use materials that are substantially equivalent for the purpose of these regulations, especially within complex assembled products. Analytical testing on representative products should be accepted rather than imposing the burden of testing for every product or part number. This approach is consistent with REACH. HP recommends allowing AAT testing on representative products rather than testing each unique product or part number.	Add §69505.3.(a)(10) If a representative product is used to generate analytical test results to support an AAT exemption claim, the responsible entity must provide a list of the brand name(s) or product name(s) for which the test results are representative. "Representative product" means a product or component from within a family of similar or related products or components that is expected to contain substantially the same amount of the CoC in equivalent locations or applications in a Priority Product.

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.4. (b)(2)	Abridged AA - Factors	This requirement to identify factors for comparison of the Priority Product and alternatives should not be required for Abridged AA Reports because Abridged AA Reports are only prepared if there is no functionally acceptable and technically feasible alternative. In these circumstances, since the alternatives have not been eliminated based on environmental or human health criteria, there is no need to complete this analysis for non-viable alternatives. Data proving that there are no alternatives that can meet functionally acceptable or technically feasible definitions should be required instead, equivalent to 69505.6(j)(2)(A)/69505.6(a)(2)(B).	
§ 69505.4. (e)	Revised Alternative Selection Decision	HP supports this provision to address alternatives identified after the Final AA Report is submitted so long as the sunset provision remains.	
§ 69505.4. (e)(3)	Sunset Requirement for Notification for Revised Alternative Selection Decision	HP supports this provision that ensures that responsible entities are subject to these Regulations for an appropriate time period.	
§ 69505.5. (a)(3)(B)	Off-ramp for Immediate Removal of CoC	HP supports the new language that allows a responsible entity to submit a Chemical Removal Intent and/or Confirmation Notifications in lieu of completing an AA.	
§ 69505.5. (b)(1)(B)	Elimination of Alternatives	HP supports the new language that allows a responsible entity to consider any identified alternative in the AA, or explain in the AA Report why an alternative is not viable for consideration.	
§ 69505.5. (c)(1)(A)	Scope of Stage 1 Analysis	HP supports the deletion of the word "all" when referring to the information required to be identified for each alternative replacement chemical under consideration, as those requirements were overly burdensome. Even without the requirement that all these factors be identified, there is still room for improvement in terms of clarifying that not all of these items be identified. See HP's extended comments on the alternatives assessment requirements for detailed suggestions on how to restructure this requirement.	<p>§ 69505.5. (c) Step 3, Initial Evaluation and Screening of Alternative Replacement Chemicals.</p> <p>(1) For those alternatives under consideration that involve removing or reducing the concentration of the Chemical(s) of Concern and using one or more alternative replacement chemicals, or otherwise adding chemicals to the product, the responsible entity shall:</p> <p>(A) Identify relevant factors for screening of replacement chemicals. A factor is relevant if it makes a material contribution in any life cycle segment to one or more:</p> <ol style="list-style-type: none"> <li>1. Adverse environmental impacts;</li> <li>2. Adverse public health impacts;</li> <li>3. Adverse impacts associated with environmental fate, physical chemical hazards, or physicochemical properties.</li> </ol> <p>The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors.</p> <p>(B) Compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product, using the relevant factors identified in subparagraph (A) as the minimum set of impact areas. Any additional impact areas may be included.</p> <p>(C) Evaluation and comparisons of alternative may be accomplished with any tool, approach, or method chosen by the entity, as long as all relevant factors are addressed. Information describing the tool, method, or approach must be included in the Preliminary AA Report.</p>

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.5. (c)(2)	Elimination of Alternatives that are worse than the CoC	The Regulations as proposed do not require a responsible entity to eliminate as an alternative replacement chemical one that has the potential to pose adverse impacts equal to or greater than those posed by the Chemical of Concern. It would seem more consistent to ensure that replacement chemicals that pose adverse impacts equal to or greater than those posed by the Chemical of Concern be considered non-viable and described under Section 69505.5(b)(1)(B).	<p><b>(2) The responsible entity must eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines does not reduce the adverse impacts in the areas that caused the original Chemical(s) of Concern to be listed.</b></p> <p>(3) The responsible entity may eliminate from further consideration in the AA any alternative replacement chemical(s) that it determines has/have the potential to pose adverse impacts equal to or greater than those posed by the Chemical(s) of Concern.</p>
§ 69505.5. (d)	Elimination of Alternatives	HP supports the new language that allows a responsible entity to eliminate an alternative from consideration if explained in the Preliminary AA Report and provided there are other alternatives to be evaluated further.	
§ 69505.5. (e)(1)	Work Plan	HP supports the clarifications and details regarding the work plan at Section 69505.7(k)(1).	
§ 69505.6. (a)(1)	Exposure in Stage 2 AA	HP recommends consideration of combining exposure pathway determinations in Section 69505.6(a)(1) and 69505.6(a)(3). See HP's extended comments on the alternatives assessment requirements for more details.	<p>(1) A factor is relevant if:</p> <p>(A) The factor makes a material contribution to materials and resource consumption and/or adverse waste and end-of-life effects associated with the Priority Product and/or one or more alternatives under consideration; or</p> <p>(B) The factor has been identified as relevant from Stage 1 and:</p> <p>1. There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives; and</p> <p>2. There is an associated exposure pathway, if applicable. The responsible entity's identification of relevant exposure pathways shall consider both of the following:</p> <p>a. Chemical quantity information:</p> <p>1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and</p> <p>2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.</p> <p>b. Exposure factors specified in section 69503.3(b).</p>

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.6. (a)(1)	Relevant Factors	<p>HP recommends that the Stage 1 analysis to be focused on relevant factors. Stage 1 could be satisfied by applying standard tools and methods, even though the complete list of 80 impact area may not be explicitly addressed.</p> <p>- If the Department is not comfortable letting entities choose their own tools and methods (out of concern that important criteria could be overlooked), a minimum set of required impact areas could be published at the time of listing the product-chemical combinations to ensure that areas of concern are specifically addressed. As an alternative, the Department could make a list of Stage 1 approved tools available in the guidance documents.</p>	<p>(A) Identify relevant factors for screening of alternatives. A factor is relevant if it makes a material contribution in any life cycle segment to one or more:</p> <ol style="list-style-type: none"> <li>1. Adverse environmental impacts;</li> <li>2. Adverse public health impacts;</li> <li>3. Adverse impacts associated with environmental fate, physical chemical hazards, or physicochemical properties.</li> </ol> <p>The responsible entity shall use available quantitative information and analytical tools, supplemented by available qualitative information and analytical tools, to identify the factors.</p> <p>(B) Compare each of the alternative replacement chemicals under consideration with the Chemical(s) of Concern in the Priority Product, using the relevant factors identified in subparagraph (A) as the minimum set of impact areas. Any additional impact areas may be included.</p> <p>(C) Evaluation and comparisons of alternative may be accomplished with any tool, approach, or method chosen by the entity, as long as all relevant factors are addressed. Information describing the tool, method, or approach must be included in the Preliminary AA Report.</p>
§ 69505.6. (a)(2)(A)	Duplicate Work	<p>DTSC has not explained how the evaluation under Section 69505.6. (a)(2)(A) differs from the evaluation required under the first stage at Section 69505.5(c)(1)(A). The Department must clarify the Regulations to distinguish the analysis to be conducted between the first stage and second stage and ensure that any duplicative analysis is eliminated. HP recommended modifying Stage 2 to focus on life cycle issues, including material and resource consumption impacts and waste and end-of life impacts, and relevant impact areas from Stage 1 that may involve trade-offs or require more detailed analyses.</p> <p>- By focusing on the resource consumption and waste impacts, standard LCA-based approaches open up as a possibility for completing the Stage 2 analysis.</p> <p>- Also, by narrowing the human health and environmental impacts to the significant ones identified in Stage 1, in depth analysis methods, such as risk assessment or MCDA, can be used. If Stage 1 is done well, there should be no need to redo the analyses in Stage 2.</p>	<p>§ 69505.6. Alternatives Analysis: Second Stage.</p> <p>After receiving approval of the Preliminary AA Report from the Department, the responsible entity shall compare the Priority Product with the alternatives still under consideration. The second stage of the AA shall include the five (5) steps described below:</p> <p>(a) Step 1, Identification of Factors Relevant for Comparison of Alternatives.</p> <p>(1) A factor is relevant if:</p> <p>(A) The factor makes a material contribution to materials and resource consumption and/or adverse waste and end-of-life effects associated with the Priority Product and/or one or more alternatives under consideration; or</p> <p>(B) The factor has been identified as relevant from Stage 1 and:</p> <ol style="list-style-type: none"> <li>1. There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives; and</li> <li>2. There is an associated exposure pathway, if applicable. The responsible entity's identification of relevant exposure pathways shall consider both of the following: <ol style="list-style-type: none"> <li>a. Chemical quantity information: <ol style="list-style-type: none"> <li>1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and</li> <li>2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration.</li> </ol> </li> <li>b. Exposure factors specified in section 69503.3(b).</li> </ol> </li> <li>(2) The responsible entity shall use available quantitative information, supplemented by available qualitative information and analytical tools, to identify the factors specified in paragraph (1)(A).</li> <li>(3) The factors identified in subparagraphs (A) and (B) are relevant for all comparisons of the Priority Product and the alternatives.</li> </ol>

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.6. (a)(2)(B)	Product function and performance	HP recommends that the product function section be simplified because performance and legal requirements have already been determined in Stage 1.	(A) Product function and performance. The responsible entity shall, at a minimum, evaluate: 1. The useful life of the Priority Product, and that of the alternatives under consideration; 2. The function and performance of each alternative relative to the Priority Product and other alternatives under consideration using the functional, performance, and legal requirements identified in 69505.5 (a)(1); and 3. Whether an alternative exists that is functionally acceptable, technically feasible, and economically feasible.
§ 69505.6. (a)(2)(C)(1)	Externalized costs	The Regulations have been revised regarding the economic impacts, but unfortunately DTSC has retained the requirement that responsible entities monetize and evaluate externalized costs. The type of economic impacts analysis required is extremely difficult to perform, particularly when there are multiple alternatives under consideration or when no alternative under consideration shows significant burden shifting. HP recommends tiering the economic analysis requirements such that eliminating the CoC and replacing it with a non-Candidate chemical requires no economic analysis, and that retaining the CoC or replacing it with a Candidate Chemical requires a complete economic analysis, including consideration of externalized costs. (Externalized costs are extraordinarily hard to calculate, and should not be required for cases where the CoC is being phased out.)	(B) Economic impacts. 1. If none of the replacement chemicals under consideration are Candidate Chemicals or Chemical(s) of Concern, no economic analysis is required. 2. If any alternative under consideration is a Candidate Chemical, or if the Priority Product with the Chemical(s) of Concern is to be retained, the responsible entity shall evaluate, monetize, and compare the following impacts of the Priority Product and the alternatives: a. Quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs; b. Public health and environmental costs; and c. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.
§ 69505.6. (a)(2)(C)(2)	Economic impacts	The Regulations have been revised regarding the economic impacts, but unfortunately DTSC has retained the requirement that responsible entities monetize and evaluate externalized costs. The type of economic impacts analysis required is extremely difficult to perform, particularly when there are multiple alternatives under consideration or when no alternative under consideration shows significant burden shifting. HP recommends tiering the economic analysis requirements such that eliminating the CoC and replacing it with a non-Candidate chemical requires no economic analysis, and that retaining the CoC or replacing it with a Candidate Chemical requires a complete economic analysis, including consideration of externalized costs. (Externalized costs are extraordinarily hard to calculate, and should not be required for cases where the CoC is being phased out.)	(B) Economic impacts. 1. If none of the alternatives under consideration are Candidate Chemicals or Chemical(s) of Concern, no economic analysis is required. 2. If any replacement chemical under consideration is a Candidate Chemical, or if the Priority Product with the Chemical(s) of Concern is to be retained, the responsible entity shall evaluate, monetize, and compare the following impacts of the Priority Product and the alternatives: a. Quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs; b. Public health and environmental costs; and c. Costs to governmental agencies and non-profit organizations that manage waste, oversee environmental cleanup and restoration efforts, and/or are charged with protecting natural resources, water quality, and wildlife.

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.6. (a)(3)	Exposure pathways	HP recommends consideration of combining exposure pathway determinations in Section 69505.6(a)(1) and 69505.6(a)(3). See HP's extended comments on the alternatives assessment requirements for more details.	(1) A factor is relevant if: (A) The factor makes a material contribution to materials and resource consumption and/or adverse waste and end-of-life effects associated with the Priority Product and/or one or more alternatives under consideration; or (B) The factor has been identified as relevant from Stage 1 and: 1. There is a material difference in the factor's contribution to such impact(s) between the Priority Product and one or more alternatives under consideration and/or between two or more alternatives; and 2. There is an associated exposure pathway, if applicable. The responsible entity's identification of relevant exposure pathways shall consider both of the following: a. Chemical quantity information: 1. Quantities of the Chemical(s) of Concern or alternative replacement chemical(s) necessary to manufacture the Priority Product and each alternative under consideration; and 2. Estimated volume and/or mass of the Chemical(s) of Concern or alternative replacement chemical(s) that is/are or would be placed into the stream of commerce in California as a result of the Priority Product and each alternative under consideration. b. Exposure factors specified in section 69503.3(b).
§ 69505.6. (b)	Comparison of Priority Products and Alternatives	HP supports DTSC's revision to remove the complex list of information to be evaluated in the comparison of the Priority Product and alternatives.	
§ 69505.6. (c)-(d)	Order of steps 3-4	HP supports DTSC's revision so that consideration of additional factors takes place before the alternative(s) are selected.	
§ 69505.6. (d)	Multiple alternatives allowed	HP supports DTSC's revision to allow the selection of more than one alternative.	
§ 69505.7. (a)(4)(A)	Redacted reports	HP supports the provision that a responsible entity claiming information in an AA Report as trade secret provide a separate publicly available AA Report with trade secret information removed. The Department could clarify here and elsewhere in the Regulations that it is only this redacted AA Report for which it would seek public comments. See, e.g., §§ 69501.5(a)(6), 69505.1(d)(2), 69505.7(i)(1).	
§ 69505.7. (b)(4)	Public Comments on Stage 1 AA	See comments above for Section 69505.1. (d)(2).	
§ 69505.7. (d)(3)	Distributor and channel partner information	Any requirement to include commercial sensitive information in a AA Report will serve as a disincentive for responsible entities to prepare a joint AA. The Department should be encouraging the development of a single AA for a particular chemical-product combination, for this will decrease review burdens and allow for uniform, fair regulatory responses. Particular responsible entity and supply chain information could be submitted later in the process in response to an audit request under Section 69508 or as part of the regulatory response. At a minimum, the Department should allow for separate attachments to the AA for individual responsible entities submitting commercially sensitive information.	Delete § 69505.7. (d)(3) in its entirety.

**ATTACHMENT 4  
ARTICLE 5**

<b>Article 5 -- Alternatives Analysis</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§ 69505.7. (i)(1)	Supporting information - response to comments	The Regulations state that Final AA Reports and final Abridged AA Reports must include a "summary of the public comments submitted" and a "description as to how the comments are addressed in the report or an explanation as to why the comments are not addressed in the AA Report." HP would ask that the Department provide more clarification regarding the procedure for responsible entities to respond to comments and particularly that responsible entities do not need to respond individually to each comment.	
§ 69505.7. (j)	Selected alternative(s)	HP supports DTSC's revision to allow the selection of more than one alternative.	
§ 69505.7. (j)(2)(C)	Disclosure of alternative chemicals	The Section seeks information on "chemicals known, based on available information, to be in the selected alternative(s) that are Chemicals of Concern, that differ from the chemicals in the Priority Product, or that are present in the selected alternative(s) at a higher concentration than in the Priority Product relative to other chemicals in the Priority Product other than Chemical(s) of Concern." HP finds this confusing and asks that the Department HP requests that the Department clarify the information it seeks. As currently written it appears DTSC is suggesting that a Chemical of Concern could be in a Priority Product at a higher concentration as part of a selected alternative, but this seems contrary to the purpose of selecting alternatives after the AA process.	
§ 69505.7. (k)(1)	Work plan content	HP supports the clarifications and details regarding the work plan at Section 69505.7(k)(1).	
§ 69505.7. (k)(2)(A)	Implementation Audits	See comments on Section 69505.2. (b)(4). The requirements here to include with the Final AA Report a plan for implementation of selected alternatives obviates the need for sensitive customer and distributor information under Section 69505.2. (b)(4).	
§ 69505.8. (b)(4)(A)	Uniform Deadlines	As noted throughout these comments, DTSC must state clearly that all AA Reports and Work Plans will have the same deadline for submission, and that an extension request granted to one responsible entity will be extended to all. Just as the Department extends a comment period for all persons based on the extension request of one, so too must the Department ensure that all AA Reports and Work Plans are submitted simultaneously to ensure that entities are treated fairly in having the same amount of time to prepare AA Reports and Work Plans. Equally importantly, entities must not be disadvantaged by the Department reviewing AA Reports and Work Plans successively and making regulatory response determinations.	The Department shall specify in a notice of compliance for a Preliminary AA Report or Alternate Process AA Work Plan the due date for submitting the Final AA Report <b>for each chemical-product combination</b> . The Department shall specify a due date that is twelve (12) months from the date the Department issues the notice of compliance, except that the Department may specify an extended due date for submission of the Final AA Report <b>for a chemical-product combination</b> if it determines based on information in <b>any of</b> the Preliminary AA Reports or Alternate Process AA Work Plans that more time is needed. The Department may also specify an extended due date for submission of the Final AA Report <b>for a chemical-product combination</b> if <b>any</b> the responsible entity submits a request under section 69505.7(k)(1)(B).

ATTACHMENT 5  
ARTICLE 6

Article 6 -- Regulatory Responses			
Section	Title	Comment	Proposed Text
§ 69506(a)	Need for Regulatory Response	As discussed in detail in HP's extended comments, a deep flaw in these proposed Regulations is that DTSC is theoretically allowed to select different regulatory responses for different responsible entities. HP finds this possibility profoundly unfair and believes it creates a situation ripe for claims of impropriety by DTSC with regard to different treatment for different entities. Also, compliance and verification of compliance within the regulated community is greatly complicated if different entities have different requirements. If DTSC is concerned, as it should be, with ensuring that its procedures are standardized, fair, and objective, then DTSC should ensure the Regulations provide a level playing field by stating that all AAs for the same chemical-product combination will be reviewed by the Department at the same time, and that DTSC will issue a uniform regulatory response. For DTSC to conduct simultaneous reviews, it must also ensure that the deadlines for submission as the same.	(a) Need for Regulatory Response. The Department shall identify and require implementation of one or more regulatory responses <b>applicable to all responsible entities</b> for Priority Products and/or selected alternative products when the Department determines such regulatory responses are necessary to protect public health and/or the environment. In selecting regulatory responses, the Department shall seek to maximize the use of alternatives of least concern when such alternatives are functionally acceptable, technically feasible, and economically feasible.
§ 69506.1 (a)	Applicability and Determination Process	The Regulations currently have an "Applicability and Determination Process" section but then also have individual applicability sections for each potential regulatory response. DTSC could simplify this Article by consolidating the applicability provisions so that each section on a regulatory response could include only those details of what the particular regulatory response would require.	
§ 69506.1 (c)	Notice of Proposed Determination	The Regulations must be revised throughout to reflect the fact that the Department will issue uniform regulatory response(s) for a particular chemical-product combination.	Notice of Proposed Determination. After issuing a notice of compliance or a notice of disapproval for a Final AA Report or a final Abridged AA Report, the Department shall issue a notice of the Department's proposed determination <b>applicable to all responsible entities for a chemical-product combination</b> that one or more of the regulatory responses specified in this article is/are required, or that no regulatory response is required.
§ 69506.3 (a)	Applicability	See comment for Section 69506.1 (a).	
§ 69506.3 ©	Communication to Consumers	See comment for Section § 69506(a).	Communication to Consumers. <del>The</del> <b>All responsible entities for a particular chemical-product combination</b> shall satisfy subsection (b)
§ 69506.3 (c)(2)	Communication to Consumers	The information required to be communicated to consumers is lengthy and will not fit directly on most product labels/packaging. Providing the information "in a prominent place" on the manufacturer's or importer's website is sufficient for most of the information to be provided to consumers. Responsible entities can provide the information at the point of sale as they see fit but it should not be required.	
§ 69506.4	Restrictions on replacement chemicals	HP supports the revisions that state the Department may impose restrictions on replacement Candidate Chemicals as that may discourage the use of other Candidate Chemicals to replace Chemicals of Concern and specifies that the Department can control replacement alternatives when necessary.	

**ATTACHMENT 5  
ARTICLE 6**

Article 6 -- Regulatory Responses			
Section	Title	Comment	Proposed Text
§ 69506.4 (a)	Creation of real <i>de minimis</i> levels	The Department could clarify that any restrictions imposed under Section 69506.4(a) on the amount of the Chemical of Concern or replacements Candidate Chemical(s) in products could (and probably would) be different from the AAT (PQL of the DTSC-published analytical method), and that it would be based on a health and safety determination.	
§ 69506.5 (a) and (b)	Existence of Safer Alternatives	See comment for Section 69506.1 (a).	
§ 69506.5 (a)	Existence of Safer Alternatives	See comment for Section § 69506(a).	the Department may require all responsible entities <b>for a particular chemical-product combination</b> to cease placing into the stream of commerce ...
§ 69506.6 (a)	Requirement for Controls.	See comment for Section § 69506(a).	the Department may require all manufacturers <b>for a particular chemical-product combination ...</b>
§ 69506.7 (a)	Applicability	See comment for Section 69506.1 (a).	
§ 69506.7 (c)	End-of-Life Program Requirements.	The Section regarding end-of-life program requirements is overly complex. The Department must review these requirements and revise to ensure that it is clear what is intended by these requirements.	
§ 69506.7 (e)	Exemption from End-of-Life Program Requirements	The Regulations have a section regarding exemptions from end-of-life program requirements and then later a section on exemptions for regulatory response requirements. Just as the applicability sections should be consolidated, so too should the exemption provisions. As currently proposed it is unclear how these two separate exemption provisions work together or separately.	
§ 69506.9 (a)	Exemptions	The Regulations have a section regarding exemptions from end-of-life program requirements and then later a section on exemptions for regulatory response requirements. Just as the applicability sections should be consolidated, so too should the exemption provisions. As currently proposed it is unclear how these two separate exemption provisions work together or separately.	
§ 69506.10 (a)	Notification to Supply Chain	It would be unnecessarily burdensome to require that responsible entities provide individual notifications to the supply chain. Providing the information in a prominent place on responsible entity's websites is sufficient for the supply chain.	The notification shall be <b>posted in a prominent place on the responsible entity's website</b> <del>sent</del> with a copy to the Department ...

**ATTACHMENT 6  
ARTICLE 8**

<b>Article 8 -- Audits</b>			
<b>Section</b>	<b>Title</b>	<b>Comment</b>	<b>Proposed Text</b>
§69508.(b)(3)-(4)	Audits and use of customer lists (distributors and channel partners)	HP believes it is inappropriate and burdensome for DTSC to ask for extensive, commercially sensitive information regarding customers and distributions within the AA Reports. If the information is needed for enforcement verification, DTSC could seek such information when it is conducting audits under Section 69508. DTSC has the authority under Section 69508 to examine compliance with Article 5 and 6 requirements, including but not limited to information related to notifications. DTSC could specify in Section 69508 that it can seek the customer and distributor information currently sought in this Section.	

**ATTACHMENT 7  
ARTICLE 9**

<b>Article 9 -- Trade Secret Protection</b>			
<b>Section</b>	<b>Title</b>	<b>Comments</b>	<b>Proposed Text</b>
§69509.(a)(6)-(7)	Assertion of a Claim of Trade Secret Protection	HP urges DTSC to ensure that its substantiation requirements focus on information necessary to meet the criteria for "trade secret." See HP's extended comments on trade secrets for detailed suggestions on how to restructure these requirements.	
§69509.1(c)	Review of Support for Trade Secret Determination	The information requested from DTSC is substantial and any company provided notice that its substantiation does not meet the criteria must be provided sufficient time to respond. Thirty days is simply too short a timeframe to allow a company to compile additional information or otherwise defend itself. There will be no substantive harm to DTSC if it affords companies more time to respond but there could be substantive, permanent harm if DTSC discloses trade secret information by not affording companies sufficient time to respond.	(c) Notice to Submitter. If the Department determines that information provided in support of a request for trade secret protection does not meet the substantive criteria for trade secret designation, the Department shall provide notice to the submitter by certified mail of its determination and that the information claimed to be trade secret will be considered a public record subject to disclosure by the Department <del>thirty (30)</del> ninety (90) days after such notice is mailed. During this <del>30</del> -day period, the submitter may seek judicial review by filing an action for a preliminary injunction and/or declaratory relief.

## ATTACHMENT 8

### Expanded List of Human Health and Environmental Areas for Stage 1 Screening

#### Expanded List of Human Health and Environmental Areas for Stage 1 Screening

##### 1. Adverse public health impacts

- (A) Carcinogenicity
- (B) Developmental Toxicity
- (C) Reproductive Toxicity
- (D) Cardiovascular Toxicity
- (E) Dermatotoxicity
- (F) Endocrine Toxicity
- (G) Epigenetic Toxicity
- (H) Genotoxicity
- (I) Hematotoxicity
- (J) Hepatotoxicity
- (K) Digestive System Toxicity
- (L) Immunotoxicity
- (M) Musculoskeletal Toxicity
- (N) Nephrotoxicity and Other Toxicity to the Urinary System
- (O) Neurodevelopmental Toxicity

##### 2. Adverse environmental impacts

###### (A) Adverse air quality impacts;

- Emissions of CA Toxic Air Contaminants# including:
- Benzene, Ethylene Dibromide (1,2-dibromoethane), Ethylene Dichloride (1,2-dichloroethane), Hexavalent chromium, Asbestos, Dibenzo-p-dioxins and Dibenzofurans chlorinated in the 2,3,7 and 8 positions and containing 4,5,6 or 7 chlorine atoms, Cadmium (metallic cadmium and cadmium compounds), Carbon Tetrachloride(tetrachloromethane), Ethylene Oxide (1,2-epoxyethane), Methylene Chloride (Dichloromethane), Trichloroethylene (Trichloroethene), Chloroform, Vinyl chloride (Chloroethylene), Inorganic Arsenic, Nickel (metallic nickel and inorganic nickel compounds), Perchloroethylene (Tetrachloroethylene), Formaldehyde, 1,3-Butadiene, Inorganic Lead, Particulate Emissions from Diesel-Fueled Engines
- Emissions of GHGs, including: Carbon dioxide, Hydrofluorocarbons, Methane, Nitrogen trifluoride, Nitrous oxide, Perfluorocarbons, Sulfur hexafluoride, or Gases that exhibit the global warming potential hazard trait, as specified in section 69405.4;
- Emissions of nitrogen oxides;
- Emissions of particulate matter that exhibits the particle size or fiber dimension hazard trait, as specified in section 69405.7;
- Emissions of chemical substances that exhibit the stratospheric ozone depletion potential hazard trait, as specified in section 69405.8;
- Emissions of sulfur oxides; or
- Emissions of tropospheric ozone-forming compounds, including compounds that exhibit the ambient ozone formation hazard trait, as specified in section 69405.1.

###### (B) Adverse ecological impacts;

- Acute or chronic toxicity;
- Changes in population size, reductions in biodiversity, or changes in ecological communities; and
- The ability of an endangered or threatened species to survive or reproduce;

- Deterioration or loss of environmentally sensitive habitats;
- Impacts that contribute to or cause vegetation contamination or damage; and
- Adverse impacts on environments that have been designated as impaired by a California State or federal regulatory agency;
- Biological or chemical contamination of soils; or
- Any other adverse effect in:#
- Domesticated Animal Toxicity
- Eutrophication
- Impairment of Waste Management Organisms
- Loss of Genetic Diversity, Including Biodiversity
- Phytotoxicity
- Wildlife Developmental Impairment
- Wildlife Growth Impairment
- Wildlife Reproductive Impairment
- Wildlife Survival Impairment

(C) Adverse soil quality impacts;

- Compaction or other structural changes
- Erosion
- Loss of organic matter
- Soil sealing

(D) Adverse water quality impacts (of the waters of the State);

- Increase in biological oxygen demand;
- Increase in chemical oxygen demand;
- Increase in temperature;
- Increase in total dissolved solids; or
- Introduction of, or increase in, any of the following:
  - CWA 303(c) pollutants# for CA including:
    - chromium III, cyanide, antimony, thallium, asbestos, acrolein, acrylonitrile, carbon tetrachloride, chlorobenzene, 1,2-dichloroethane, 1,1-dichloroethylene, 1,3-dichloropropylene, ethylbenzene, 1,1,2,2-tetrachloroethane, tetrachloroethylene, 1,1,2-trichloroethane, trichloroethylene, vinyl chloride, 2,4-dichlorophenol, 2-methyl-4,6-dinitrophenol, 2,4-dinitrophenol, benzidine, bis(2-chloroethyl)ether, bis(2-ethylhexyl)phthalate, 3,3-dichlorobenzidine, diethyl phthalate, dimethyl phthalate, di-n-butyl phthalate, 2,4-dinitrotoluene, 1,2-diphenylhydrazine, hexachlorobutadiene, hexachlorocyclopentadiene, hexachloroethane, isophorone, nitrobenzene, n-nitrosodimethylamine, n-nitrosodiphenylamine.
  - CWA 303(d) pollutants# for CA including:
    - Arsenic, Cadmium, Chromium VI, Copper, Lead, Manganese, Mercury, Nickel, Selenium, Silver, Zinc, Boron and Chloride salts, PCBs.
  - Safe Drinking Water Act pollutants with MCLs including:#
  - Antimony, Arsenic, Asbestos, Barium, Beryllium, Cadmium, Chromium, Copper, free Cyanide, Fluoride, Lead, Mercury (inorganic), Nitrate (measured as Nitrogen), Nitrite (measured as Nitrogen), Selenium, Thallium, Acrylamide, Benzene, Benzo(a)pyrene (PAHs), Carbofuran, Carbon tetrachloride, Chlorobenzene, o-Dichlorobenzene, p-Dichlorobenzene, 1,2-Dichloroethane, 1,1-Dichloroethylene, cis-1,2-Dichloroethylene, trans-1,2-Dichloroethylene, Dichloromethane, 1,2-Dichloropropane, Di(2-ethylhexyl) adipate, Di(2-ethylhexyl) phthalate, Dioxin (2,3,7,8-TCDD), Epichlorohydrin, Ethylbenzene, Ethylene dibromide, Polychlorinated biphenyls (PCBs), Styrene, Tetrachloroethylene, Toluene, 1,2,4-Trichlorobenzene, 1,1,1-Trichloroethane, 1,1,2-

- Trichloroethane, Trichloroethylene, Vinyl chloride, Xylenes
- o CA HSC 116455 with Notification Levels including:#
- o Boron, n-Butylbenzene, sec-Butylbenzene, tert-Butylbenzene, Carbon disulfide, Chlorate, 2-Chlorotoluene, 4-Chlorotoluene, Dichlorodifluoromethane (Freon 12), 1,4-Dioxane, Ethylene glycol, Formaldehyde, HMX, Isopropylbenzene, Manganese, Methyl isobutyl ketone (MIBK), Naphthalene, N-Nitrosodiethylamine (NDEA), N-Nitrosodimethylamine (NDMA), N-Nitrosodi-n-propylamine (NDPA), n-Propylbenzene, RDX, Tertiary butyl alcohol (TBA), 1,2,3-Trichloropropane (1,2,3-TCP), 1,2,4-Trimethylbenzene, 1,3,5-Trimethylbenzene, 2,4,6-Trinitrotoluene (TNT), Vanadium
- o CA Safe Drinking Water Act with public health goals# including:
- o 1,1-Dichloroethane, 1,1-Dichloroethylene, 1,1,1-Trichloroethane, 1,2-Dibromo-3-chloropropane, 1,2-Dichloroethane, 1,2-Dichloroethylene, cis, 1,2-Dichloroethylene, trans, 1,2-Dichloropropane, 1,1,2-Trichloroethane, 1,1,2,2-Tetrachloroethane, 1,2,3-Trichloropropane, 1,2,4-Trichlorobenzene, 1,2-Dichlorobenzene, 1,4-Dichlorobenzene, 2,4-Dichlorophenoxyacetic acid, Aluminum, Antimony, Arsenic, Asbestos, Barium, Benzene, Benzo[a]pyrene, Beryllium, Bromate, Cadmium, Carbofuran, Carbon Tetrachloride, Chlorite, Chlorobenzene, Hexavalent Chromium, Copper, Cyanide, Dichloromethane, Diethylhexyl adipate, Diethylhexylphthalate (DEHP), Ethylbenzene, Ethylene dibromide, Fluoride, Gross Alpha or Beta Particle Activity, Hexachlorobenzene, Hexachlorocyclopentadiene, Lead, Mercury (inorganic), Methyl tertiary butyl ether (MTBE), N-Nitrosodimethylamine, Nickel, Nitrate, Nitrate and Nitrite, Nitrite, Perchlorate, Polychlorinated Biphenyls (PCBs), Radium-226, Radium-228, Selenium, Strontium-90, Styrene, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), Tetrachloroethylene, Thallium, Toluene, Trichloroethylene, Trichlorofluoromethane (Freon 11), Trichlorotrifluoroethane (Freon 113), Tritium, Uranium, Vinyl Chloride, Xylene

(E) Exceedance of an enforceable California or federal regulatory standard relating to the protection of the environment.

### 3. Environmental fate;

- (A) Aerobic and anaerobic half-lives;
- (B) Aqueous hydrolysis half-life;
- (C) Atmospheric oxidation rate;
- (D) Bioaccumulation;
- (E) Biodegradation;
- (F) Mobility in environmental media, as specified in section 69405.6;
- (G) Persistence; and
- (H) Photodegradation.

### 4. Physical chemical hazards

- (A) Combustion Facilitation
- (B) Explosivity
- (C) Flammability

### 5. Physicochemical properties

- (A) Physical state;
- (B) Molecular weight;
- (C) Density;
- (D) Vapor pressure and saturated vapor pressure;
- (E) Melting point;
- (F) Boiling point;
- (G) Water solubility;
- (H) Lipid solubility;

- (I) Octanol-water partition coefficient, octanol-air partition coefficient, organic carbon partition coefficient;
- (J) Diffusivity in air and water;
- (K) Henry's Law constant;
- (L) Sorption coefficient for soil and sediment;
- (M) Redox potential;
- (N) Photolysis rates;
- (O) Hydrolysis rates;
- (P) Dissociation constants; or
- (Q) Reactivity including electrophilicity



February 28, 2013

Krycia Von Burg  
Department of Toxic Substances Control  
Regulations Section  
PO Box 806  
Sacramento, CA 95812-0806

Re: Safer Consumer Products Revised Regulations

Dear Ms. Von Burg:

On behalf of the International Fragrance Association North America (IFRA North America) and its membership, we appreciate this opportunity to comment on the Department of Toxic Substances Control's (DTSC) Safer Consumer Products Revised Regulations (Regulations).

IFRA North America is the principal trade association representing the interests of the U.S. fragrance industry. Our members create and manufacture fragrances and scents for personal care, home care, industrial and institutional use as well as home design products, all of which are manufactured by consumer goods companies. Our Association also represents companies that source and supply individual fragrance ingredients, such as essential oils and other raw materials, which are used in perfumes and fragrance mixtures.

Throughout the regulatory development process, IFRA North America has consistently advocated for revisions in an effort to make the Regulations more effective and efficient. Our members have a strong record of prioritizing and advancing public health and the well-being of the environment. This, in part, is the result of an unwavering commitment to innovation. On behalf of our many member companies which represent over ninety percent of the fragrance market by volume in North America, we continue to have a strong interest in the Regulations and incorporate where relevant, each of our previously submitted comments by reference in this letter including those most recently submitted on October 11, 2012. Further, we recognize

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and associate our comments with those drafted by the Green Chemistry Alliance through which detailed comments have been provided regarding the various iterations of the Regulations.

### **Some Improvements, but More Work is Necessary**

After thorough review of the revised Regulations, it is evident that DTSC has attempted to address many of the comments raised by industry; several of which resulted in positive and essential modifications. We appreciate the considerable effort DTSC has invested to revise the Regulations and recognize that significant progress has been made since the draft regulations were initially released.

Specifically, IFRA North America was pleased to see DTSC's revision to the title of the initial list of chemicals now referred to as 'Candidate Chemicals' rather than 'Chemicals of Concern.' This change in nomenclature helps to ensure that a consumer (or our members' customers) does not make unwarranted assumptions that a material is unsafe prior to its being properly assessed. This is an important distinction and we applaud this decision made by DTSC.

Along these same lines, we believe DTSC made a positive modification in eliminating the provision requiring that an Alternative Analysis (AA) be conducted by a certified assessor. The revised requirements are less burdensome and considerably more feasible for manufacturers to comply with. However, it is important to point out that while the revision will help simplify the process of performing an AA, it will not sacrifice the quality of the report or how it is prepared. This is a critical change and is representative of how DTSC can engage with stakeholders to find a solution acceptable to all parties.

While we very much appreciate the revisions in the aforementioned areas, IFRA North America is concerned that there still remains areas of the regulation that do not sufficiently mitigate many of the unnecessary burdens on business while providing significant benefits to public health and the environment. IFRA North America continues to be fully supportive of the principles behind the Regulations, however we believe critical improvements remain to be achieved.

Specifically, our Association and its member companies remain highly concerned with two specific areas: the lack of a fixed de minimis and the inadequate protection of trade secrets. These concepts are outlined below in more detail accompanied by potential solutions for DTSC's consideration in hopes of achieving a balanced and well-rounded regulatory blueprint that ensures the health of the public and the environment as well as the health of businesses in California and beyond.

## **A Fixed De Minimis is Necessary to Provide Predictability and Eliminate Improbable Risks**

As stated in our previously filed comments, IFRA North America's gravest concern is the absence of a fixed de minimis provision in the Regulations. We are confident that DTSC recognizes that the de minimis or 'virtually safe' approach is used across a wide array of regulatory schemes beyond the U.S. and is generally regarded as necessary to weed out sufficiently improbable risks. This is acknowledged by a number of global government and regulatory bodies and aids in not only eliminating unnecessary and overwhelming paperwork for both the Department and industry alike, but also ensures the consumer is not presented with information that can be misleading at best.

A default de minimis level provides certainty and predictability to the regulated community allowing them to fully understand their compliance responsibilities. We urge DTSC to recognize that without a clear and articulated threshold, our members will likely go through an extremely burdensome and potentially destabilizing process, forcing them to incur unnecessary expenses that have no bearing on objective safety. It is crucial for the regulated community to have predictability as it goes through this substantial and comprehensive overhaul of how all consumer products and their ingredients are formulated and created. Though this holds true for all businesses, it is especially true for small and medium sized companies of which our membership is based.

Moreover, IFRA North America recommends that DTSC set a fixed de minimis or threshold that is consistent with a majority of state, federal and international regulations. Again we incorporate our Association's previously filed comments which refer to other international frameworks which set a concentration of 1000 parts per million of an intentionally-added chemical in a finished product. In addition, we refer DTSC to approaches taken by other states including Washington and Maine that set clear threshold levels of 0.1% by weight for reporting.

## **The 'Masking' Mechanism Should Be Expanded to Account for Trade Secrets**

IFRA North America and its members are appreciative of DTSC's efforts to recognize that our industry's most valuable asset lies within its intellectual property. Enormous investments in research and development go into creating not just fragrance mixtures but also the individual ingredients that attract and excite consumers. In some cases, the disclosure of a single ingredient or group of ingredients could provide competitors with a critical piece of the puzzle that would allow them to reproduce the product. The only practicable legal way to protect fragrance formulas and ingredients is under state and federal trade secret laws. However there is concern that the Regulations, as currently drafted, threaten this vital aspect of our members' intellectual property.

While we were pleased to see DTSC's attempt to address the protection of intellectual property via a 'masking' mechanism, we remain concerned that this form of protection is currently limited to those materials that are patented or subject to a patent application. Trade secrets remain the most practical and efficient means of protecting the intangible assets produced by the fragrance industry. For the purposes of our industry, patents are typically only used to protect newly developed technologies or newly discovered individual fragrance materials. Patents are not a practical means by which to protect the innovative and creative effort utilized in order to create a fragrance formula. Moreover, the time necessary to obtain a patent often exceeds the product life cycle of many new fragrances. Given these circumstances, the 'masking' mechanism would not provide any benefit or protection to the fragrance industry's intellectual property.

Therefore IFRA North America urges DTSC to expand the revised regulations, and allow for the masking of ingredients for not only those for which patents are being sought, but also for those materials that contribute to a proprietary fragrance and would therefore fall under the protection of a trade secret.

IFRA North America is appreciative that DTSC understands the fundamental importance that trade secrets hold for our unique industry and urges the Department to make changes necessary to ensure the very core of this industry.

## **Conclusion**

IFRA North America continues to remain a strong advocate for public health as well as the environment and again, we recognize and appreciate the efforts put forth by DTSC. However, we strongly encourage the department to continue to work with the regulated community of stakeholders to finalize a workable, practical and defensible proposal.

Sincerely,

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

Jennifer Abril  
Executive Director



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February 28, 2013

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

**Re: Intertek Comments on California Department of Toxic Substances Control – Proposed Regulation, “Safer Consumer Products”**

Dear Ms. Von Burg:

Intertek appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) regarding its January 2013 draft of “Proposed Regulations for Safer Consumer Products (regulations).

**Intertek**

Founded over 100 years ago by Thomas Edison as Electrical Testing Laboratories (ETL) to test the safety and performance of incandescent bulbs and lamps, Intertek is today a world leader in providing testing, inspection and certification services for a wide range of products and processes. Intertek maintains over 1,000 labs and offices in over 110 countries and manages over 150 certification programs, including many for consumer products.

Intertek routinely participates in and comments on statutory and regulatory developments affecting consumer goods in North America and globally, including those relating to chemical content. Intertek lab and other personnel are literally at the cutting edge of existing and emerging chemical compliance and quality assurance issues in an ever more complex and rapidly evolving global supply chain environment. In our view, it is not just desirable but, indeed, essential for the Department and the State of California work with responsible testing labs like Intertek to find real-world and low-cost solutions to the growing complexity of U.S. and international chemical safety laws and requirements. Otherwise, the “compliance gap” between those with and those without the resources to fully internalize and comply with CPSC laws will continue to grow, benefiting neither consumers, the Department, nor the regulated marketplace.



## Comments

While Intertek appreciates the progress made by the Department in developing successive versions of these draft regulations, including significant progress represented by this latest version, we remain very concerned about several key aspects of the regulations that we believe could ultimately cripple the ability of the Department to effectively administer this regulatory scheme and that will undoubtedly confuse both industry and consumers alike. Thus we respectfully submit the following:

- **De Minimus Threshold.** The final regulations should contain establishment of individual *de minimus* levels for contaminant chemicals and more thoroughly and practically define the circumstances under which DTSC would consider a chemical to be intentionally added vs. merely contaminant chemicals. The proposed use of Practical Quantification Limits as the threshold at which a chemical would be considered to be a contaminant is practically and logically flawed since levels below PQLs cannot, by definition, be reliably measured and since PQLs depend on continually evolving instrumentation and methods. In addition, manufacturers should not be required to affirmatively apply for *de minimus* exemptions, which undermines the very purpose of an exemption process. Rather, firms should only be required to notify the DTSC of Priority Products containing Chemicals of Concern at levels below the Alternative Assessment threshold. These changes would help make the final regulations more workable and consistent with similar laws in Washington State and Maine.
- **Inaccessible Components.** If a component is inaccessible, after reasonably foreseeable use and abuse of a product, by definition the chemicals in that component will not cause human or environmental exposure, absent scientifically reliable information of the ability of the chemicals in that component to readily migrate outside of that component. This fact should be explicitly recognized in the final regulations, as it is under U. S. Consumer Product Safety Commission (CPSC) law and in many other comparable regulatory contexts. Relatedly, the term “contaminant” should explicitly include any concentration of a chemical that is contained in an inaccessible component of a product, since that chemical would not pose an exposure concern.
- **Chemical Selection Process.** The process for selecting priority (“candidate”) chemicals should be more definitively spelled-out and should be based on actual risk assessment rather than mere exposure since exposure, absent a hazard, creates no consumer or other risk. And there must be found to be definitive and direct links between exposures and risks for each specific chemical in question before a chemical is so listed. Such is consistent with other US and European regulatory schemes and is also consistent with sound scientific and regulatory



principles. Finally, there must be adequate cost analysis incorporated into this candidate chemical selection process, including for the initial five chemicals selected.

- **Confidential Business Information.** All CBI should be protected from disclosure in the final regulation. Protecting only “trade secrets” or chemical formulations for which patents have been secured or filed is wholly inadequate to protect valid intellectual property and information and creates a significant, negative incentive to full compliance with the regulations. Relatedly, the Department should afford every affected firm a reasonable opportunity to comment on and object to the release of any company or product-specific information where the affected company can be ascertained, as is the case with the CPSC and in other regulatory contexts. Failure to do so is fundamentally unfair and will inevitably lead to widespread consumer confusion and misinformation.
- **Clarification of Chemicals Already Regulated by Another Entity.** While these are ostensibly made exempt in the draft regulations with regard to chemicals regulated for the same potential impacts, the DTSC’s discretion to move forward to list such chemicals in order to “meaningfully enhance” human or environmental protection is far too vague and subjective and that this exception that is likely to swallow the rule should therefore be deleted.
- **Degradation of Chemicals.** The final regulations should clarify that only chemicals that are likely to degrade into Candidate Chemicals should be included in determining the existence of an Adverse Impact, not those where such an occurrence is merely possible.
- **Parties Submitting Alternative Assessments.** Finally, Intertek suggests that the final regulations make clear that any person, duly authorized, may submit AAs on behalf of another person or entity. Doing so will help alleviate unnecessary duplication of effort and ensure that AAs are submitted more efficiently.

Thank you for the opportunity to submit these comments. I and/or other Intertek personnel would be most happy to discuss any aspect of the pending regulations in more detail with the Department or other interested persons.

Respectfully Submitted,



Joseph P. Mohorovic  
Vice President, Government Relations  
Intertek NA



February 28, 2013

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

Via Electronic Submission

**Re: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (January 2013)**

IPC – Association Connecting Electronics Industries appreciates the opportunity to comment on the above referenced draft Safer Consumer Product Alternatives Regulation. We recognize and appreciate the effort DTSC has invested in developing the current draft. We support DTSC’s decision to rename the list of lists as “Candidate Chemicals,” add an Administrative Procedures Act process for updating Priority Products list, focus the scope for Alternatives Analyses, and remove of the third party certified assessor requirement. However, we are concerned that the Candidate Chemicals list remains overly broad and that the Alternatives Analysis should not be subject to public review and comment.

DTSC’s approach in the Safer Consumer Products Regulation should be scientifically based. Substances that exhibit the greatest hazards, such as those known to cause cancer, developmental or reproductive harm, be persistent, bioaccumulative and toxic (PBT) in the environment, and pose the greatest exposure to consumers, should be given priority. When evaluating consumer products to be covered by the regulation, DTSC must consider the level of exposure to the priority chemicals in order to ensure the utmost protection to human health and the environment. By considering both hazard and exposure when identifying chemical-product combinations to be evaluated, DTSC will make the biggest reduction in risk to human health and the environment.

IPC encourages DTSC to consider implementation of our proposed alternative provisions that would make the regulation more effective in protecting human health and the environment. We appreciate the opportunity to provide the following comments.

**About IPC**

IPC, a U.S. headquartered global trade association, represents all facets of the electronic interconnection industry, including design, printed board manufacturing and electronics assembly. Printed boards and electronic assemblies are used in a variety of electronic devices that include computers, cell phones, pacemakers, and sophisticated missile defense systems. IPC has over 3,300 member companies, including over 250 member companies located in California.

IPC strongly supports cost effective, science-based environmental initiatives and has been active in a number of voluntary environmental programs including EPA's Design for the Environment partnership projects, the development of the Electronic Product Environmental Assessment Tool (EPEAT) standard<sup>1</sup>, and the development of the Greener Chemicals and Process Information Standard<sup>2</sup>, developed through the American Chemical Society and the National Standards Foundation.

### **DTSC Should Evaluate the Scientific Merit for Each Chemical Identified as a Candidate Chemical**

IPC believes that the proposed scope of Candidate Chemicals is overly broad. We believe that a more focused scope would allow DTSC to better achieve the goals of the legislation by focusing on those chemicals most likely to affect human health and the environment.

While IPC agrees with DTSC's proposal to identify chemicals to be considered for listing as Chemicals of Concern as "Candidate Chemicals," we urge DTSC to be cautious about placing chemicals on the Candidate Chemicals list. We are gravely concerned that the Candidate Chemicals list will have the negative connotation of a black list of chemicals. For example, the EU REACH Regulation Substances of Very High Concern (SVHC) list establishes a notification requirement, not a ban. However, the SVHC list is viewed by many as a list of banned substances resulting in manufacturers removing SVHCs from their products without conducting an alternatives assessment to ensure the substitutes are better for human health and the environment. Companies may view the Candidate Chemicals list in the same way as the SVHC list and remove Candidate Chemicals before conducting an Alternatives Analysis, which could result in unintended consequences, if the chosen alternative poses a higher risk to human health and the environment.

If DTSC decides that publishing a list of lists of Candidate Chemicals is unavoidable, it is critical the agency provide a clear, scientific explanation for the list's content. Providing an explanation will provide both the public and industry with information on why certain chemicals are listed. Including a sound explanation for chemical listing will help avoid panic among the public by providing the necessary background information for informed decisions. An explanation for chemical listings may also prevent regrettable substitution by industry by reducing the pressure to remove Candidate Chemicals from their products. Furthermore, the list of lists proposed by DTSC contains lists of chemicals from multiple countries and U.S. states. Each list has a different set of criteria for evaluating chemicals and therefore the conclusions regarding the hazard potential of a particular chemical may be inconsistent among the lists. Any inconsistency between the lists' conclusions on a particular chemical could cause stakeholders to question DTSC's credibility. DTSC should provide a summary of available data, including but not limited to a literature review, available toxicity data, and available exposure data for each Candidate Chemical instead of providing a list of lists. DTSC should provide an explanation for why a chemical is listed as a Candidate Chemical.

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<sup>1</sup> <http://www.epeat.net/>

<sup>2</sup> NSF/GCI/ANSI 355

[http://www.nsf.org/business/sustainability/product\\_greener\\_chemicals.asp?program=Sustainability](http://www.nsf.org/business/sustainability/product_greener_chemicals.asp?program=Sustainability)

## **DTSC Should Establish a De Minimis Threshold; Using a PQL is Inappropriate**

DTSC should create a clearly defined, science-based de minimis threshold value for the Candidate Chemicals. The creation of a de minimis value would help to focus regulatory implementation on the most significant uses of chemicals presenting the highest risk to human health and the environment. DTSC should not presume that the mere presence of an identified Candidate Chemical is reason to suggest potential harm. Without a de minimis threshold, valuable resources would be spent on conducting an alternatives analysis on a COC that is present in Priority Products in only trace amounts. Using valuable resources on insignificant uses of chemicals would result in a minimal benefit to human health and the environment at great cost to industry and DTSC. Establishing a de minimis will help ensure that the most significant uses of Candidate Chemicals are addressed.

DTSC's proposal to utilize the Practical Quantification Limit (PQL) as a threshold value for COCs in Priority Products is inappropriate. A PQL is the lowest quantity of a substance that can be measured. Just because a chemical can be measured does not mean it is a risk to human health or the environment. Laboratory test methods are continuously improving and are increasingly able to detect smaller and smaller trace amounts of chemicals. DTSC should focus its efforts on the most significant amounts of chemicals in order to ensure valuable state and industry resources are spent on conducting and evaluating Alternative Analyses for chemicals presenting the highest risk to human health and the environment.

## **IPC Supports DTSC's Decision to Initially Focus the Priority Products List in Order to Implement a Workable Regulation**

IPC supports DTSC's decision to initially focus the regulation on no more than five Priority Products. This is a practical approach that will enable DTSC to implement the regulation and learn what works and does not work and make adjustments accordingly. A regulation that is focused on a small number of specific products will allow DTSC to use available resources more efficiently and implement a manageable regulation to protect human health and the environment.

IPC commends DTSC for proposing to establish an Administrative Procedures Act (APA) process for updating the Priority Products list. An APA process will allow for transparency throughout the implementation of the regulation. Opening up subsequent Priority Product lists to stakeholder review and comment will provide DTSC with valuable feedback on their proposed Priority Products list. Stakeholders, specifically manufacturers of products proposed to be listed as Priority Products, are the most knowledgeable on the chemical composition of their product. Therefore, manufacturers can provide DTSC with important information to inform DTSC's decision on whether to finalize the product listing. DTSC should implement an APA process for updating the Priority Products list in order to be transparent.

## **DTSC Should Prioritize Chemicals in Priority Products**

When identifying chemical-product combinations, DTSC should prioritize the chemicals within each product that deem that product as a Priority Product. Once DTSC has determined that a Candidate Chemical is the basis for a product-chemical combination being listed as a Priority

Product, that chemical is then considered a Chemical of Concern (COC). Requiring manufacturers to conduct simultaneous AAs for multiple COCs in a Priority Product would be overly burdensome, especially for small businesses. Prioritizing COCs in Priority Products would allow manufacturers to focus on the chemicals that present the highest risk to human health and the environment. DTSC should prioritize the COCs in Priority Products if multiple COCs are found in a product in order to ensure the chemicals presenting the highest risk to human health and the environment are addressed first.

### **IPC Supports Proposed Alternative Analyses Process but Remains Concerned About Public Review and Comment Requirement**

IPC applauds DTSC for acknowledging the importance of identifying safer alternatives prior to replacing a COC. Confirming an alternative chemical is safer than the original chemical prior to replacing it will ensure that the changes result in improved human health and environmental protection. Furthermore, a thorough evaluation of the alternative chemical will ensure that the product functions properly, resulting in consumers having access to products that meet their expectations. Fully evaluating alternatives will also help ensure unintended consequences do not occur. For example, the European Union did not study the alternatives when they restricted the use of lead in electronics under the RoHS Directive. The U.S. EPA lead-free solder study<sup>3</sup> evaluated the environmental impacts of tin-lead solder versus lead-free alternative solders. The study found that the increased energy use associated with the higher operating temperatures required for manufacturing lead-free soldered electronics would cause higher air pollution, acid rain, stream eutrophication and global warming impacts than tin-lead soldered electronics. EPA's study serves as an important reminder that alternatives need to be fully evaluated before substitution in order to provide improvement to human health and the environment.

IPC supports DTSC's proposal to focus the AA on only the COC, alternative replacement chemical and any other chemical in the alternative that differs from those chemicals already contained in the product. The proposed streamlined approach will help ensure that the COCs are the chemicals being evaluated. DTSC's proposal will also encourage effective use of resources by both manufacturers and DTSC to conduct and evaluate, respectively, such a comprehensive AA because only the highest priority chemicals will be evaluated.

IPC also supports DTSC's proposal to offer extensions for up to three years for conducting the AA. However, we are concerned that the proposed requirement that extension requests be made by each manufacturer would be extremely burdensome for DTSC to evaluate and industry to file, especially small companies. Almost all manufacturers impacted by a Priority Product listing are likely to request the additional time to conduct an AA. We recommend that DTSC grant an industry-wide extension if an extension request is granted in order to reduce the burden on manufacturers and DTSC.

IPC supports the removal of the third party certified assessor requirement for AAs. However, DTSC's proposal to require public review and comment of AAs is not a good substitute. Stakeholders generally are not scientific experts and their feedback could misguide the AA

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<sup>3</sup> U.S. Environmental Protection Agency. August 2007. Solder in Electronics: A life Cycle Assessment. Available at <http://www.epa.gov/dfe/pubs/solder/lca/>.

process. The process for evaluating AAs would be better served by qualified experts reviewing AAs. As an alternative to a public review and comment process, DTSC should consider implementing a qualified reviewer requirement for all AAs. This qualified reviewer could be a toxicologist, environmental consultant, an expert in AAs, or another qualified entity. In order to ensure stakeholder comments are heard, the qualified reviewer would hear stakeholder comments through a public meeting forum. The qualified reviewer would then take stakeholder comments into consideration when evaluating a manufacturer's AA. The qualified reviewer would then issue a report on the manufacturer's AA that would include a summary of the stakeholder comments and how they were addressed in the AA. Implementing a qualified reviewer requirement would ensure public comments are heard and the burden on manufacturers would be reduced.

## **Conclusions**

IPC is a strong advocate for scientifically-based environmental regulations that improve environmental conditions, protect human health, and stimulate the economy. We urge DTSC to take our suggestions into account when finalizing the regulation in order to ensure human health and environmental protection.

## Comments on Safer Consumer Products Regulation

- JEITA (Japan Electronics and Information Technology Industries Association)  
 CIAJ (Communications and Information network Association of Japan)  
 JBMIA (Japan Business Machine and Information System Industries Association)  
 JEMA (Japan Electrical Manufacturers' Association)

page	Clause/ Subclause	Comments	Proposed change
		<p>We would like to express our concerns on revised draft Safer Consumer Products Regulation.</p> <p>Despite your honest devotion to improve the draft regulation, we believe the draft regulation is still remains to be unreasonable trade barrier, as regulatory impact is unable to assess: draft regulation should clearly state subject product(s) and chemical(s), assess regulatory impact with socio-economical consideration, and to be placed on public comment.</p> <p>We share concerns of ACC, European Union and Japanese Government, expressed in previous public consultation closed on October 11, 2012 that the draft regulation seems to be inconsistent with TBT agreement. These essential points should be taken seriously and be properly addressed before further progress in drawing up the regulation.</p> <p>Our points are as follows;</p> <ol style="list-style-type: none"> <li>1. Draft Safer Consumer Products regulation is nominally intended to regulate all consumer products, requires Alternate Analysis(AA)/ replacement of certain chemical with alternative based on hazard property of the chemical, and there are no similar regulation around the world.</li> </ol>	

		<p>Essentially, AA with consideration of risk tradeoff described in the draft regulation have difficulty with verification of scientific evidence, and there are great technical uncertainty on the implementation of the substitution of the chemical. Furthermore, AA will be time consuming and requires unaffordable burden, however benefit to be earned will have great uncertainty. In addition to this, draft regulation do not designate subject product(s) and chemical(s), only state that DTSC will designate them later, and no one can evaluate benefit on the reduction of risk and expected cost of the draft regulation. As a result, validity and rationality of the draft regulation could not be evaluated.</p> <p>2. Considering international stream of commerce, there will be significant influence on the international society as wide spectrum of chemicals, including chemicals in the article (manufactured item) will be regulated, validity and rationality of the draft regulation should be well verified, harmonized with and shared with stakeholders not only insider but also outsider of the state of California.</p> <p>3. Subject product(s) and chemical(s) should be clearly stated in the draft regulation, and at least, regulatory impact assessment under Executive Order of the United States 12991 should be proceeded, verified the validity and rationality of the draft regulation, then the result of the assessment should be placed on the public comment along with the draft regulation.</p>	
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7	SS69501.1. Definition (6) “Adverse public health impacts”...	This definition here says the “Public health includes occupational health”. As this regulation takes care of “consumer products”, this definition to include “occupational health” does not sound adequate.	The sentence “Public health includes occupational health” should be deleted.
16	SS69501.2. Duty to Comply and Consequences of Non-Compliance.	The total lead-time through supply chain to produce a consumer product is, though each player trying hard to reduce it, quite long, and each portion of the supply chain is always keeping some amount of inventory at each stage.	The restriction to a product containing Chemical of Concern should consider sufficient time frame by balancing the time to allow to eliminate those inventory in a reasonable manner and the hazard caused by them. This is to avoid unnecessary disposal of materials and half-products, which may cause another kind of environmental impact.
23	Article2. SS69502.2. Candidate Chemicals Identification.	We are concerned that the process to identify the Candidate Chemicals is quite dependent on DTSC’s study and decision. At considering Candidate Chemicals, quite a lot of them are not scientifically proved to be hazardous, but concerned. In such a circumstance, each stakeholder should have each different opinion. Without receiving all of these opinions and holding discussions among them, the determination may not be considered fair.	

25	SS69502.2 Candidate Chemicals Identification. (b) Additions to the Candidate Chemicals List	We understand the importance of updating/adding the Candidate Chemicals to the list, however, we also would like to emphasize that such chemical information should also consider other regulations such as EU REACH. It would be burdensome for the industry if they need to take care of each of the regulations, which have the same kind of purpose worldwide and individually, therefore, we want this regulation to closely work with other countries'/areas' authority to take care of chemical controls, with the view to harmonize the approach.	
26	SS69502.3. Candidate Chemicals List. (c)(1)	As written in Article 2 Section 69502.2, some of the chemicals are not explicitly hazardous, and some do not have enough information either to say yes or no to such nomination. Under such situation, also considering such public comment information may not directly be aware by chemical manufacturers by the reason we mentioned in "Section 69501.2 Duty to Comply and Consequences of Non-Compliance., (b)(1)(B)/(C), (2)(A)", the public comment period (forty-five(45)days) sounds too short. We hope that the time frame like defined in EU REACH should be considered.	

28	Article 3. Process for Identifying and Prioritizing Product –Chemical Combinations SS69503.2. Product-Chemical Identification and Prioritization(b)(2) Other Regulatory Programs	Adding to California regulations, federal laws and international agreements, other major areas’ (such as EU) regulation shall also be considered This is with the view to try to harmonize the scope or the chemicals in the list.	
P35 、 P36	69505(a) (b)	<p>69505(a) and (b) stipulate that the Department of Toxic Substances Control (hereinafter “DTSC) must release ‘guidance materials’ and ‘example of Alternative Analysis (hereinafter “AA”)’ on its website for the implementation of AA, before Responsible entities implement AA.</p> <p>Meanwhile, impact assessment on public health and environment etc. in AA required for implementation by Responsible entities have issues in that it is generally not easy to be conducted*1, and the results may easily vary depending on the conductor of the impact assessment when the implementation method is not specifically provided.</p> <p>In order to respond to the issues above, we would request DTSC to verify*2 the feasibility of specifically implementing AA with use of ‘guidance materials’ and ‘example of AAs’ by Responsible entities, prior to the</p>	<p>We propose adding the following underlined parts to § 69505(a) and (b).</p> <p>§ 69505. Guidance Materials.</p> <p>(a) Guidance Materials. Before finalizing the initial list of Priority Products, the Department shall make available on its website guidance materials to assist persons in performing AAs in accordance with this article, <u>after conducting public review for comments</u>. The Department shall periodically revise and update the guidance materials after conducting public review for comments.</p> <p>(b) Sample Alternatives Analyses. The Department shall also post on its website examples of AAs that are available in the</p>

		<p>release of the 'guidance materials' and 'example of AAs' on the website.</p> <p>To be specific, we request a public consultation be launched prior to release, and the 'guidance materials' and 'example of AAs' be established/released after taking sufficient time and communication with industries and academic/evaluation organizations.</p> <p>*1: Unlike impact assessments for chemical substances and preparations, implementation of impact assessment for articles are particularly difficult due to the identification of the exposure scenario and few generally-accepted evaluation methods.</p> <p>*2: Examples of verification:</p> <ul style="list-style-type: none"> <li>• Is the impact assessment method feasible for various products, or for products by various manufacturers with different specifications of the covered product?</li> <li>• With respect to the implementation of AA, is the evaluation of the current product/substance or the trial production/evaluation of the alternative product/substance economically reasonable?</li> </ul>	<p>public domain at no cost, <u>after conducting public review for comments</u>. The posting must indicate, for each AA, the name of the person or entity that prepared the AA.</p>
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46	Article 5. Alternatives Analysis (Comment 1)	<p>The activity related to AA seems quite dependent onto each company's activity.</p> <p>It is understandable that each company has its right to research and develop by its own, but, on the other hand, the possible alternative chemicals to the same kind of products should be quite limited, therefore, each of those companies may come up with the same conclusion, sometimes with the report to say "no alternative". If they come up with such possible same kind of result, all of those various but the same activity multiplication seem wasteful both from social cost or environmental burden point of view.</p> <p>We want DTSC to consider establishing some kind of body like EU SIEF for AA activity either at Priority Product or Chemicals of Concern level, while each company can detain the right to individually investigate and report. At the same time DTSC should provide the information openly to those who need them, unless they are categorized as "trade secret", so that those who would perform AA activity could refer to some of the information.</p>	
46	Article 5. Alternatives Analysis (Comment 2)	<p>In case of semiconductor industry, due to its advanced technology nature, the selection of a chemical takes a long research and development time, including the approval phase by the assembly product. Sometime, starting from the very first stage of selecting the potential alternative to actual first mass-production out, it takes like ten (10) to fifteen (15) years. The importance of reducing or elimination the Chemicals of Concern is fully understood by the industry, however, considering above, the time</p>	

		frame needed to switch to an alternative sometimes takes such time mentioned above. We hope that DTSC would understand such nature of the industry at considering AA activity.	
50	SS69505.7. Alternatives Analysis Reports. (d) Responsible Entity and Supply Chain Information.	As written in “trade secret”, the player’s information in the supply chain is a part of business confidential information. At the same time, the names of the further upstream or the downstream in the supply chain to a player than the direct supplier or the customer are not disclosed, therefore, such information cannot be provided.	This portion shall be deleted entirely.
57	Article 6. Regulatory Response SS69506.1 Applicability and Determination Process. (d)(1)	Many companies selling consumer products in California have a headquarter function (to read such regulations) located outside of California. For them, to receive public consultation information may take time. Sometimes, it takes time to read English, when it is not their native tongue. Considering this, forty-five (45) days seems too short to comment.	The public comment period should be longer, such as sixty (60) days.
60	SS69506.3. Product Information for Consumers. (c)(2)(A)	We are concerned with the possible confusion related to the change management if the (c)(2)(A) is strongly required. We foresee that some of the products have some label while others do not under the same product name in the same sales area in the market at a changing time. That may confuse some of the consumers, while it is not practical to say that all the labels on the product package would be	We suggest that website or POP (point of purchase) card information at the shop should also be selected.

		changed over a night.	
63	SS69506.7. End-of-Life Management Requirements.(c)	<p>This section seems to say that each company is requested that they not only fund but establish and maintain a management system to the end-of-life. We believe such system should be established mostly by the district government</p> <p>We understand that somebody should fund such activity, but the establishment and maintenance of its system is a different issue. This should cause chaos in end-of-life management, if each company tries to have its own and different system. We hope that such system should be considered as a part of waste management of California government, and through such study, funding method shall also be discussed.</p>	We propose that EU WEEE method be studied.
71	Article 9. Trade Secret Protection SS69509. Assertion of a Claim of Trade Secret Protection.	The trade secret mentioned here seems too much onto the engineering and know-how issue. However, in the daily course of business, those information related to supply chain or the plan of R&D are confidential business information. Especially, the consumer product companies or its direct upstream companies are NOT mostly chemical manufacturers. Most of the cases, their names are unknown.	We request that the definition of trade secret shall be reconsidered to include those information. Also, from this point of view, we want DTSC to consider to limit requested information to minimum level to achieve the purpose of this regulation..



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February 28, 2013

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

**Re: Safer Consumer Products Draft Regulations (January 29, 2013)**

Dear Ms. Von Burg:

On behalf of the Japan Chemical Industry Association (JCIA)<sup>1</sup>, we respectfully submit the following comments relative to the Department of Toxic Substances Control's (DTSC) draft Safer Consumer Products Regulations of January 29, 2013. These comments supplement JCIA's October 11, 2012, comments.

JCIA is grateful for the opportunity to comment on the revised proposed regulations described in the above title. We appreciate the improvements made in the new proposal and believe some of these modifications may address JCIA's initial concerns. Some problems remain in the revised proposal, however, causing serious concern for us. We summarize those issues of concern below.

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<sup>1</sup> JCIA, which has about 170 member companies and about 80 organizations engaged in the manufacturing and handling of chemical products, promotes the stable development of the chemical industry in Japan and beyond. As a member of the International Council of Chemical Associations (ICCA), consisting of the world's chemical associations, JCIA has engaged in voluntary global initiatives to resolve issues faced by chemical companies and associations throughout the world, including matters related to the environment, the safety of chemicals, and measures to prevent global warming.





February 28, 2013  
Page 2

## 1. Chemical of Concern List/Candidate Chemical List

JCIA continues to be concerned with the number of chemicals to be included on the Candidate Chemical list, which was previously referred to as the Chemical of Concern list. As we noted in our October 2012 comments, the number of substances in the initial list is much larger than comparable regulatory lists, such as the U.S. Environmental Protection Agency (EPA) TSCA Work Plan Chemicals list, the European Union's (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations list of substances of very high concern (SVHC), and the Japanese Chemical Substances Control Law Priority Assessment Chemical Substances. The discrepancy between the number of chemicals on the DTSC Candidate Chemical list and these other regulatory lists will cause great concern over the impact of the California program on business activities and society in general. In addition, we are concerned that the Candidate Chemical list can be quickly expanded to include other chemicals, furthering the problem of an unreasonably large list of chemicals.

JCIA appreciates the revision made by DTSC to change the term "Chemicals of Concern" to "Candidate Chemicals." This change may help clarify that DTSC has not made a determination that a "Candidate Chemical" is a "Chemical of Concern" within a particular product. We continue to suggest, however, that DTSC provide a clear disclaimer that inclusion on the Candidate Chemical list is NOT a determination by DTSC that the chemical in question is a concern in any particular product.

JCIA also continues to urge DTSC to develop a rigorous prioritization process or committee review procedures to select the candidate chemical-priority product combination. A more transparent prioritization process with clear selection criteria will assist both the public and impacted stakeholders in understanding current and future expectations.

## 2. Alternative Analysis (AA)

While we are pleased that DTSC eliminated the assessor and accreditation bodies provisions in this updated draft, we continue to be concerned with the significant burden associated with the alternatives analysis requirement. The actions needed to complete the





February 28, 2013  
Page 3

analysis are extremely complicated and would be enormously difficult for small to medium enterprises (SME) that do not have the expertise or resources to complete. Therefore, we request that DTSC simplify the AA procedures to focus on those criteria specified in AB 1879 (i.e., volume of the chemical in commerce, the potential for exposure in a consumer product, and potential effects on sensitive subpopulations) and avoid duplication of analysis between the Preliminary and Final AA Reports. Furthermore, as noted in our previous comments, the proposed timeframe of 180 days to complete a preliminary analysis is simply too short and must be extended.

### 3. Responsibility for Compliance with the Regulations

We are disappointed that the revised draft regulations do not expressly encourage consortia formation, as we suggested in our October 2012 letter. JCIA fully supports the option for the regulatory requirements to be fulfilled by a consortium, trade association, or other entity acting on behalf of the manufacturer, importer, or retailer, as we believe it will provide the most effective manner for its members to engage in the regulatory process, and will reduce DTSC burdens and resources if it can review, for example, one AA report prepared by a consortium than several AA reports prepared by individual responsible entities. We again encourage DTSC to review the regulations regarding the AA and regulatory response processes and add provisions that would encourage responsible entities to form consortia when conducting AAs. This would include but is not limited to providing information on conditions and operation procedures for consortia formation, as they are not described in the revised draft regulations.

### 4. Revised Definition of Alternative Assessment Threshold (AAT)

JCIA does not support the DTSC revised AAT provision in the current draft. As proposed, the AAT would be the practical quantification limit for the substance but the exemption would only apply to contaminants. We do not support this change as it is not scientifically justified and could set thresholds artificially low, and much lower than necessary to protect human health. This would result in additional burden, time, and resources by impacted industries. It also unnecessarily limits the threshold exemption to contaminants when what should matter is the presence of the substance, whether a contaminant or not.





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February 28, 2013  
Page 4

For further information regarding the Japan Chemical Industry Association,  
please visit the JCIA website at <http://www.nikkakyo.org/>

Sincerely Yours,

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

Fumiaki Shono, Ph.D.  
Executive Director  
Chemicals Management Department  
Japan Chemical Industry Association

**Page 9**

(16) “Assembler”

*This needs some clarity. Manufacturers often contract with “assemblers” to build the products they then sell. An “assembler”, as defined in this rule, should not be under contract with a manufacturer and should be building product to sell under their own brand or as “generic”. Under these circumstances they select components based on functionality and cost (and availability, etc.), but usually not chemical content (but they might begin to once this regulation comes into force!).*

**Page 11**

9 (23)(A) “Component” means a uniquely identifiable homogeneous material, item, part, piece,  
10 assembly, or subassembly that is a necessary or intended element of a  
11 consumer product. A component may be comprised of one or more homogeneous materials.

*A “homogeneous material” is not a “component” in the parlance of the manufacturing world. A part, item, component, or piece is comprised of one or more homogeneous materials; a sub-assembly, module, or assembly is comprised of more than one parts, items, components, or pieces (terminology varies). See below for how this impacts further definitions.*

*Including “homogeneous material” in the definition of “Component” creates problems for later uses of the term in the regulation. As suggested, including a sentence describing how homogeneous materials relate to a “component” eliminates these problems.*

**Page 14**

17 (44) “Manufacturer” means any person who manufactures a product that is subject to the  
18 requirements of this chapter, or any person that controls the  
19 manufacturing process for, or has the capacity to specify, directly or indirectly, the use of  
chemicals in,  
20 such a product.

*Add the clause “DIRECTLY OR INDIRECTLY”; Indirect would be to specify a part that provides a certain functionality, like a screw, without specifying exactly what chemicals that screw is composed of.*

*Note that you have to be very careful about how you distinguish “Manufacturer” from “Assembler” in this sense. An assembler will often want to buy a specific part or item “off the shelf” to use in the assembly of a consumer product. They don’t just use “found” items. In a way this can be seen as “indirectly” specifying “the use of chemicals in such a product.” It is extremely indirect because they not only have no say in the chemical composition of what they are buying, similar to the “Manufacturer” who specifies a specific screw, but they also have no say in how it is actually manufactured or – if it is an assembly itself – assembled..*

*I think a clearer distinction needs to be made between “assembler” and “manufacturer”. In fact, the rationale for defining “assembler” is unclear as the term is never distinguished from “retailer” in the text of the regulation; Assemblers are always indicated together with retailers*

*(but not vice-versa) and generally subject to the same requirements because of it. Perhaps examples are needed.*

## Page 15

(50)(A) –“Placed into the stream of commerce in California”

*The term “component” is used here in “a component in an assembled product”. This is clumsy given how it is defined before as (possibly) a specific homogeneous material. An “assembled product” is an assembly of items that may be comprised of one or more “components” (as defined herein). You do not “assemble”, in the sense the word is defined on Page 9 (15), homogeneous materials into a consumer product. You may “fabricate” an integrated circuit through deposition of homogeneous materials into a die which you then assemble into an “item”, which is further “assembled” into a consumer product (and there may be further “assembly” steps as well). You may plate, paint, or anodize a sheet of metal, thereby creating another homogeneous material layer on it. We should discuss the terminology used for manufacturing here...*

## Page 17

19 (59) “Replacement Candidate Chemical” or “replacement chemical” means ...

23 (A) A chemical that is not present in the Priority Product; or

24 (B) A chemical that is present at a lower concentration in the Priority Product relative to  
25 other chemicals in the Priority Product other than the Chemical(s) of Concern.

*This is potentially problematic. If the COC is in a homogeneous material at a high concentration, yet is still a small percent by weight of the Priority Product, what if the replacement chemical happens to appear elsewhere, possibly by chance, in the priority product, without relation to the “component”? Suddenly it can’t be used to replace the COC!*

*Redefine it to mean “A chemical or group of chemicals that the manufacturer designates to replace the COC”. It should not be tied to whether or not it appears elsewhere in the Priority Product.*

Michael Kirschner  
February 27, 2013

February 28, 2013

Kryisia Von Burg, Regulations Coordinator  
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P.O. Box 806  
Sacramento, CA 95812-0806

Via Mail and Email: [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

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

Dear Ms. Von Burg:

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

The Proposed Regulations as currently constructed do not incorporate the plethora of suggestions provided by KII, GCA and several trade associations, and continue to be unworkable, fundamentally flawed and may not pass legal review. If the Proposed Regulations are finalized, the effective implementation could suffer major delays while these issues are addressed. Although we are providing our comments to DTSC on the Proposed Regulations as written, KII strongly encourages DTSC to focus on regulatory alternatives, such as the proposal submitted to DTSC by GCA on November 1, 2010, that have a greater chance of being implemented, passing legal review and achieving the stated objectives of the AB 1879. Government Code §11346.2(b)(5). For the record a copy of that early proposal is available at: [http://www.greenchemistryalliance.org/Media/DTSC\\_SCPA\\_GCA\\_Comment\\_Ltr20101101.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1](http://www.greenchemistryalliance.org/Media/DTSC_SCPA_GCA_Comment_Ltr20101101.pdf?phpMyAdmin=0qAMLokPorOw9YHA07a2Qay4IJ1).

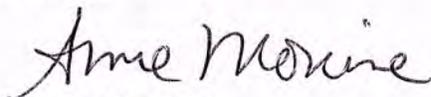
Krycia Von Burg  
Page 2  
February 28, 2013

Although the Trade Association Comments detail the majority of KII's comments and concerns, Attachment A outlines additional concerns, comments and suggestions on the Proposed Regulations. Based on all of these continued concerns, KII must encourage DTSC to once again consider **not finalizing** the Proposed Regulations and to earnestly work with the regulated community to draft regulations that will efficiently and effectively implement the intent and purpose of AB 1879 and SB 509. The Trade Association Comments elaborate on these fundamental flaws and provide specific citations and examples to help DTSC understand why the Proposed Regulations have not met the requirements of the Administrative Procedures Act nor the California Environmental Quality Act. Specifically, DTSC has failed to draft the regulation "in plain, straightforward language, avoiding technical terms as much as possible, and using a coherent and easily readable style." Government Code §11346.2(a)(1). Furthermore, as pointed out by several commenters on previous drafts, the Proposed Regulations potentially amount to a technical barrier to trade under the World Trade Organization Agreement. In addition, the Proposed Regulations are contrary to Executive Order 13609 (May 1, 2012) Promoting International Regulatory Cooperation and do not align with the direction of the Federal Government to prevent barriers to international trade.

KII supports and incorporates by reference the detailed Trade Association Comments submitted in response to DTSC's Proposed Regulations. As currently written, the Proposed Regulations will likely result in increased cost of products in California, impacts to the availability of products, increased cost disparities, and due to compliance risk concerns may encourage California businesses to seek more attractive business environments outside the state, with little discernible benefit to the citizens of California.

Should you have any questions, KII would welcome the opportunity to provide further clarification. Please contact our California representative, Dawn Koepke ([dkoepke@mchughgr.com](mailto:dkoepke@mchughgr.com), 916-930-1993) for further information.

Sincerely,



**Anne Monine**  
Corporate Director, Environmental Excellence

### Attachment A

#### A. The Proposed Regulations Lack Clarity and Provide Unauthorized Discretion to DTSC

Two of several issues underlying KII's concerns with the Proposed Regulations are that as drafted, this version is even more vague than previous versions, and in several areas confers even greater discretion on the DTSC than previous versions. In addition, because the structure of the current version is more complex and difficult to follow, DTSC has increased the difficulty for the regulated community to interpret the requirements and ensure that the proper compliance protocols can be followed. This lack of clarity and increased complexity results in a Responsible Entity being required to comply with the regulation when it has no clear understanding of DTSC's expectations for compliance. As a result, the Responsible Entity must consume additional time and resources to provide more information than necessary or potentially face repeated resubmissions to meet DTSC's expectations. This also creates risk to Responsible Entities for non-compliance with the regulations due to difficulty in interpretation.

#### B. DTSC has Failed to Consider Alternatives to the Proposed Regulations That Would Enable the Regulated Community to More Efficiently Comply with the Intent of the Underlying Statute

The Proposed Regulations continue to be onerous and oppressive by forcing the responsible entities to collect and communicate large amounts of information that may not contribute to the ultimate selection of an alternative for a Priority Product. All that the disclosure of this information will do is to provide excessive amounts of unnecessary information that will take a significant amount of time and resources to generate, rather than allowing the regulated community to determine the most efficient path towards identifying the required safer alternative. The Proposed Regulations fail to recognize the core competencies and expertise within Responsible Entities that, if availed by DTSC, may facilitate the selection of an appropriate alternative in a more efficient and effective manner than the process as laid out by the Proposed Regulations. Neglecting to draw upon this capability results in significant resources being consumed in "bureaucratic busywork" for no measureable benefit to the underlying statute's stated objective of protecting the health, safety and environment of the citizens of California. The end result will be increased costs to consumers for the products sold in California, reducing product choice, diversion of company resources away from other important research and development activities, organizations deciding not to do business in California or deciding not to expand product lines or businesses. A more efficient use of limited resources would be for DTSC to shift focus to the alternative selected by the Responsible Entity and the benefits that alternative would confer rather than the unnecessary information collection on alternatives that are not selected.

### C. Confidential Business Information is not Adequately Protected

The Proposed Regulations continue to fail to recognize the value and sensitivity of Confidential Business Information (CBI). The Trade Secret Provisions identified in this version appear to be directed primarily at patents and patentable technology. The legislative intent of AB 1879, clearly states: "The bill would establish a procedure for the protection of information submitted to the department that is claimed to be a trade secret." The Proposed Regulations fail to offer protection to the broader range of CBI by intending to solicit and publicly post CBI including customer lists, product margins, supply chain information and other valuable and protected information. KII agrees with the GCA comments that this is a clear departure from the recently released Administration Strategy on Mitigating the Theft of U.S. Trade Secrets. The regulated community must have the opportunity and option to protect confidential information, developments, innovative chemical identities or other trade secrets in the submission of Alternative Assessments. It is essential that these protections are not stripped away by the language used in the Proposed Regulations. By eliminating options, DTSC is proposing a regulation that will amount to a regulatory taking of the intellectual property of the Regulated Entities. The Proposed Regulations fail to account intellectual property laws and what companies must do to protect sensitive information.

### D. DTSC Has Not Been Provided the Authority to Implement the Precautionary Principle

In the current version of the regulation, DTSC has moved its discretion and authority to a precautionary principle approach and away from the intent of the underlying statute, which is to develop a process "by which chemicals of concern in products, and their potential alternatives, are evaluated to determine how best to limit exposure or to reduce the level of hazard posed by a chemical of concern." AB 1879, Section 1. This shift is evidenced by DTSC's replacement of the term "ability" with "potential" and "impact" with "effect". These seemingly subtle word changes, when coupled with the reduction of the Alternatives Analysis Threshold Limit to the Practical Quantitation Limit ("PQL"), have the cumulative impact of creating an unreasonably precautionary approach. DTSC should revise the regulation to be consistent with the authority granted it by the underlying statute.

The following are comments concerning two specific areas within the Proposed Regulations:

- Section 69501.1(12): Alternatives Analysis Threshold - KII agrees with GCA and other Trade Associations that DTSC's introduction of the Practical Quantitation Limit (PQL) and incorporation of the PQL into the Alternatives Analysis Threshold Definition results in a meaningless and unworkable threshold. The PQL is a laboratory procedure and has no health or exposure elements. DTSC must recognize and incorporate a meaningful *de minimis* threshold in the Proposed Regulations for intentionally added chemicals. A *de*

minimis threshold or the safety evaluation proposed by GCA would provide Regulated Entities with the direction needed to focus on real changes that could have some health and safety improvements in products.

- Section 69501.1(16): Assembler –The introduction of this new terminology within the context of determining who is the Responsibility Entity adds further confusion and complexity to implementing the regulation. It is unclear when a company stops being a manufacturer and starts being an assembler. Equally, the meaning of the term “Component” (definition 23) is difficult to determine. These changes create a supply chain issue that may not have been intended or anticipated by the drafters of the Proposed Regulations. For instance, component manufacturers for complex products are unlikely to have sufficient information available to them from their customers, the product assemblers, to evaluate the efficacy and impacts of alternatives to the finished assembled product. This would be especially true if there is more than one component in a priority product that is the source of a chemical of concern triggering AA requirements for the other component.

As KII understands the Proposed Regulations, in order to conduct a full life cycle impact analysis of alternatives, detailed information of other components manufactured by other suppliers would need to be available to the entity now defined to be the “manufacturer”. The other component suppliers are likely to be competitors; therefore it is unrealistic to require the flow of information about alternatives and potentially sensitive or proprietary information between these competitors. In many instances, the assembler often controls the content in the final product and demands that components meet certain specifications, functionality, or may restrict the use of certain chemicals or substances for compatibility purposes. However, for other components, the component manufacturer will specify the raw materials to be used, the manner in which the product is to be manufactured as well as the acceptance of the finished product; if that is the case the component manufacturer should be the primary responsible entity for ensuring compliance. The complexity of the supply chain and which entity controls the finished product may differ based on the product category, complexity of the product, and/or the commoditized nature of the components.

It is also unclear whether DTSC intended to include formulators of chemicals in the definition of component or assembler. If several chemical products, each containing several component chemicals, are mixed, it could be interpreted that the formulator would be considered by DTSC to be an assembler or a manufacturer.

By not using generally accepted industrial nomenclature, DTSC is creating confusion and compliance risk to the regulated community, and increasing transaction costs which will result in higher cost of products to CA consumers but unlikely to have commensurate health benefits. In addition to increasing the cost of products, limiting product

availability, and increasing price disparity for consumers in California; the negative impacts to companies may include diversion of resources away from research and development activities, encouraging companies to locate outside of California, and deciding not to expand operations or product lines available in the state.

- § 69503.2 Product-Chemical Identification and Prioritization Factors.

*(a)(1) There must be **potential public** and/or aquatic, avian, or terrestrial animal or plant organism **exposure** to the Candidate Chemical(s) in the product; and  
(2) There must be the potential for one or more exposures to contribute to or cause **significant or widespread** adverse impacts.*

The lack of definition of the above highlighted terms creates uncertainty as to how the terms should be interpreted and how DTSC will evaluate chemicals and products for prioritization. It is unclear whether the terms will be interpreted based on actual exposure data and information concerning impacts or if exposure proxies such as quantities and content will be used. If the latter, exposure proxies fail to properly assess the potential for these impacts and is further evidence of a shift to a precautionary principle approach.



February 27, 2012

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

**Re: Draft Safer Consumer Products Regulations**

Dear Ms. Von Burg,

The Los Angeles Area Chamber of Commerce (“L.A. Area Chamber”) appreciates the opportunity to comment on the Department of Toxic Substances Control’s (“DTSC”) revised draft Safer Consumer Products Regulations (the “Regulations”).<sup>1</sup> The L.A. Area Chamber seeks full prosperity for the Los Angeles region. As a trustee for the current and future welfare of the region, the L.A. Area Chamber champions economic prosperity and quality of life. It serves a diverse membership of businesses of every size, from nearly every industry, in every community across Los Angeles County, and represents more than 1,600 members and more than 650,000 employees.

The L.A. Area Chamber has reviewed the comments submitted to DTSC by the Orange County Business Council (copy attached). We agree with and endorse those comments. The L.A. Area Chamber requests that DTSC undertake additional analysis before promulgating final regulations, including: a robust economic impact analysis as required by CAPA; selection, with notice and comment, of the initial Candidate Chemicals; and development of an EIR as required by CEQA.

Sincerely,

A handwritten signature in cursive script that reads "Gary Toebben".

Gary Toebben  
President & CEO

Attachment

1. DTSC, Safer Consumer Products Proposed Regulations, R-2011-02 (Jan. 2013), available at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf> (last visited Feb. 26, 2013).



GAIL FARBER, CHAIR  
MARGARET CLARK, VICE CHAIR

LOS ANGELES COUNTY  
SOLID WASTE MANAGEMENT COMMITTEE/  
INTEGRATED WASTE MANAGEMENT TASK FORCE  
900 SOUTH FREMONT AVENUE, ALHAMBRA, CALIFORNIA 91803-1331  
P.O. BOX 1460, ALHAMBRA, CALIFORNIA 91802-1460  
[www.lacountyiswmtf.org](http://www.lacountyiswmtf.org)

February 28, 2013

Kryisia Von Burg  
Department of Toxic Substances Control  
Regulations Section  
PO Box 806  
Sacramento, CA 95812-0806

Dear Ms. Von Burg:

### **COMMENTS REGARDING PROPOSED DRAFT REGULATIONS FOR SAFER CONSUMER PRODUCT ALTERNATIVES**

The Los Angeles County Integrated Waste Management Task Force (Task Force) would like to express our support for, and appreciates the opportunity to comment on, the proposed regulations for Safer Consumer Product Alternatives (Regulations) that the Department of Toxic Substances Control (DTSC) is currently developing. The Regulations are an integral part of California's Green Chemistry Initiative, and the Task Force appreciates the involvement of affected stakeholders and the general transparency of the process and would like to offer the following comments:

#### Section 69501 Purpose and Applicability:

- 1. Definitions** –The terms “recycling,” “recyclability,” and “capture rate” should be clearly defined for the purposes of these regulations.
- 2. Applicability and Non-Duplication** – Section 69501(b)(3)(A) should be deleted. It is imperative that household hazardous waste products are not excluded from these regulations. DTSC's ability to regulate discarded products that may contain water pollutants or other constituents should not be thwarted. As presently written, the section appears to imply exclusion based solely on regulation of emissions/discharges rather than regulation of the product itself. Products with any pollutants or constituents which would cause them to be deemed household hazardous waste should not be allowed to be excluded from these regulations.

#### Section 69506.7. End-of-Life Management Requirements:

- 3. Program Performance Goals** – Product Stewardship program performance goals should be set by the State in consultation with affected stakeholders including manufacturers and local governments that bear an enormous cost

burden associated with the current end-of-life management of the products. Additionally, due to the fact that not all hazardous consumer products are recyclable, end-of-life management requirements should not exclude or prohibit the beneficial use of hazardous waste/materials, including but not limited to energy production, and should encourage source reduction. As such, we suggest the following language starting at Section 69506.7(c)(2)(H):

*Program performance goals established by the Department in consultation with the manufacturers or stewardship organization and affected stakeholders, which shall be quantitative to the extent feasible, for: 1. Increasing the capture rate of covered products at the end-of-life; and 2. Increasing recyclability, and recycling rate, and beneficial use; and 3. reducing waste generation. (I) A description of how each program performance goal will be achieved by the manufacturer or stewardship organization.*

4. **Annual Reports** – With transparency in mind, producer responsibility systems should require audited financial statements in the annual reports. This is especially critical to make certain that funds raised to implement the end-of-life management plan are not used to fund litigation against DTSC or other State departments. Therefore, we suggest the following language for Section 69506.7, starting at Section 69506.7(c)(5):

*The report must include, by total tonnage: (A) The quantity, by total tonnage, of products placed into the stream of commerce in California over the previous one-year period; and (B) The quantify, by total tonnage, of products recovered over the same one-year period; and (C) an independent financial audit of the end-of-life management program. The audit should be conducted in accordance with auditing standards generally accepted in the United States of America and standards set forth in Government Auditing Standards issued by the Comptroller General of the United States or other auditing standards as approved by the Department.*

5. **Alternative End-of-Life Programs** – In order to allow effective, flexible, and diverse programs with consumer convenience in mind, producer responsibility systems should not be limited to retail take-back as the sole collection mechanism. As such, we suggest the following language beginning at Section 69506.7(d):

*Alternative End-of-Life Programs. A manufacturer subject to compliance with requirements of this section may request the Department's approval to substitute an alternative end-of-life management program that*

*achieves, to the maximum extent feasible, the same results as the program required by this section. ~~A manufacturer may not propose an in-store take back program as part of an alternative program unless the manufacturer provides in the plan evidence that a sufficient number of retailers have agreed in writing to participate~~ If a manufacturer's alternative end-of-life program relies on other persons to achieve its capture or recycling rates be it retailers, contractors, or others, manufacturers must provide written substantiation of their participation to insure successful implementation of the plan as proposed.*

- 6. Sales prohibition** – The section implies but does not explicitly state that non-compliant manufacturers are prohibited from selling relevant products in the State. In order to clarify the intent, we suggest adding the following statement to the end of Section 69506.7(a):

*A manufacturer of a product subject to compliance with requirements of this section that is not in compliance with this section must cease placing the subject product into the stream of commerce in California directly or indirectly.*

- 7. Management of products that retain a Chemical of Concern** – The end-of-life management section seems to preclude DTSC from requiring management of products that retain a Chemical of Concern during a long phase out period. Specifically, Section 69506.7(a) seems to conflict with Section 69506.1(a)(3). To clarify, we suggest the following language to Section 69506.7(a):

*Applicability. A manufacturer of a selected alternative, a Priority Product that will remain in commerce in California pending development and distribution of a selected alternative, or a Priority Product for which an alternative is not selected...shall comply with the requirements of subsection (c) except as otherwise provided under subsections (d) and (e).*

Section 69509. Assertion of a Claim of Trade Secret Protection:

- 8. Trade Secret Protection** – This Chapter should not allow a manufacturer's private, non-disclosure agreement to prevent disclosure of information to the Department. ~~Allowing two private parties to agree to hide information would set a dangerous precedent.~~ We recommend the following changes to Section 69509(c):

*Documentation. A person who asserts a claim of trade secret protection shall also at the time of submission provide the Department with both of*

Kryisia Von Burg  
February 28, 2013  
Page 2

*the following: (1) Except where expressly prohibited by federal law, ~~or by a nondisclosure agreement whose relevant text is provided to the Department,~~ a complete copy of the documentation being submitted, which shall include the information for which trade secret protection is claimed and (2) A redacted copy of the documentation being submitted, which shall exclude the information for which trade secret protection is claimed.*

Again, thank you for the consideration of our comments and the transparent nature of the development of these important regulations. We look forward to continue working constructively with DTSC on this and other related issues. If you have any questions, please contact Mr. Mike Mohajer of the Task Force at [MikeMohajer@yahoo.com](mailto:MikeMohajer@yahoo.com) or (909) 592-1147.

Sincerely,



Margaret Clark, Vice-Chair  
Los Angeles County Solid Waste Management Committee/  
Integrated Waste management Task Force and  
Council Member, City of Rosemead

GA:ts

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cc: Debbie Raphael, Director, Department of Toxic Substances Control  
Matt Rodriguez, Secretary of the California Environmental Protection Agency  
Each Member of the County of Los Angeles Board of Supervisors  
California State Association of Counties  
California Product Stewardship Council  
League of California Cities, Los Angeles Division  
Southern California Association of Governments  
San Gabriel Valley Council of Governments  
South Bay Cities Council of Governments  
Gateway Cities Council of Governments  
Each City Recycling Coordinator in Los Angeles County  
Each Member of the Los Angeles County Integrated Waste Management Task Force

# MARIN COUNTY HAZARDOUS AND SOLID WASTE MANAGEMENT JOINT POWERS AUTHORITY

Belvedere:  
Mary Neilan

February 21, 2013

Corte Madera:  
David Bracken

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

County of Marin:  
Matthew Hymel

Fairfax:  
Garrett Toy

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

Larkspur:  
Dan Schwarz

Dear Director Raphael,

Mill Valley:  
Jim McCann

The Marin County Hazardous and Solid Waste Management Joint Powers Authority (JPA) is a regional agency formed following AB 939 to ensure proper handling of waste in Marin County. JPA membership includes all of Marin's cities and the County of Marin.

Novato:  
Michael Frank

Ross:  
Rob Braulik

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

San Anselmo:  
Debbie Stutsman

San Rafael:  
Nancy Mackle

Sausalito:  
Adam Politzer

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.

Tiburon:  
Margaret Curran

While we strongly support the proposed regulations, we suggest that you make the following modifications.

Section 69501. Purpose and Applicability:

(1) **Definitions** – Section 69501.1 should be expanded to provide clear definitions of the terms "recycling," "recyclability" and "capture rate."

- (2) **Applicability and Non-Duplication** – The language regarding overlapping regulatory programs appears to interfere with the Department's ability to regulate discarded products that may contain water pollutants or other constituents that would make them regulated household hazardous wastes. Specifically, it appears to allow exclusion based on regulation of the pollutant in emissions or discharges (e.g., Clean Air Act, Clean Water Act) rather than regulation of the product itself. Products containing water pollutants or other constituents which would cause them to be deemed household hazardous waste should not be allowed to be excluded from this Chapter. *It is exceptionally important that household hazardous waste products not be excluded from these regulations. To clarify, we suggest deleting Section 69501(b)(3)(A) (page 5, starting on line 20).*

Section 69506.7. End-of-Life Management Requirements:

- (3) **Program performance goals** – In order to ensure the proper role of government in any producer responsibility system, the State should establish the performance standards in consultation with the manufacturers, as well as other affected stakeholders, such as local government agencies that bear a cost burden associated with the current end of life management of the product. The manufacturers or stewardship organizations should identify how to attain those standards in their stewardship plans, and report on their progress annually. Additionally, it should be noted that not all hazardous products are recyclable and can only be used "beneficially" to produce energy. As such, the end-of-life management requirements should not exclude or prohibit the beneficial use of hazardous materials, and should encourage source reduction. Therefore, we suggest the following language (page 63, starting on line 37): (H) Program performance goals established by the Department in consultation with the manufacturers or stewardship organizations and affected stakeholders, which shall be quantitative to the extent feasible, for: 1. Increasing the capture rate of covered products at the end-of-life; and 2. Increasing recyclability, and recycling rate, and beneficial use; and 3. reducing waste generation. (I) A description of how each program performance goal will be achieved by the manufacturer or stewardship organization.
- (4) **Annual reports** – In order to ensure transparency, any producer responsibility system should require audited financial statements in the annual reports. This is especially critical to make certain that funds raised to implement the end of life management plan are not used to fund litigation against DTSC or other State departments. Therefore, we suggest the following language (page 63, starting on line 18): (5)...The report must include, by total tonnage:(A) The quantity, by total tonnage, of products placed into the stream of commerce in California over the previous one-year period; and (B) The quantity, by total tonnage, of products recovered over the same one-year period; and (C) an independent financial audit of the end-of-life management program. The audit shall be conducted in accordance with auditing standards generally accepted in the United States of America, and standards set forth in Government Auditing Standards issued by the Comptroller General of the United States.

- (5) **Alternative End-of-Life Programs** – In order to allow effective, flexible and diverse programs, producer responsibility systems should not be limited to retail take-back as the sole collection mechanism. Therefore, we suggest the following language (page 64, starting on line 25): *(d) ...A manufacturer subject to this section may request the Department's approval to substitute an alternative end-of-life management program that achieves, to the maximum extent feasible, the same results as the program required by this section. ~~A manufacturer may not propose an in-store take-back program as part of an alternative program unless the manufacturer provides in the plan evidence that a sufficient number of retailers have agreed in writing to participate. If a manufacturer's alternative end of life program relies on other persons to achieve its capture or recycling rates, be it retailer, contractors, or others, manufacturers must provide written substantiation of their participation to insure successful implementation of the plan as proposed.~~*
- (6) **Sales prohibition** – The end-of-life management section implies but does not explicitly state that non-compliant manufacturers are prohibited from selling subject products in the State. To clarify the intent, we suggest adding the following statement to the end of section 69506.7.(a) (page 62, starting on line 34): *A manufacturer of a product subject to this section that is not in compliance with this section must cease placing the subject product into the stream of commerce in California, directly or indirectly.*
- (7) **Management of products that retain a Chemical of Concern** – The end-of-life management section [69506.7(a)] seems to preclude the Department from requiring management of products that retain a Chemical of Concern during a long phase out period. Specifically, 69506.7(a) seems to conflict with 69506.1(a)(3). To clarify, we suggest the following language (page 62, starting on line 30): *(a) Applicability. A manufacturer of a selected alternative, a priority product that will remain in commerce in California pending development and distribution of a selected alternative, or a Priority Product for which an alternative is not selected... shall comply with the requirements of subsection (c) except as otherwise provided under subsections (d) and (e).*

Section 69509. Assertion of a Claim of Trade Secret Protection:

- (8) **Trade Secret Protection** – This Chapter should not allow a manufacturer's private non-disclosure agreement (e.g., an agreement between a chemical supplier and a manufacturer) to prevent disclosure of information to the Department. Allowing two private parties to agree to hide information from the State seems very inappropriate and sets a dangerous precedent. Therefore, we recommend the following changes (starting on page 72, line 41): *(c) Documentation. A person who asserts a claim of trade secret protection shall also at the time of submission provide the Department with both of the following: (1) Except where expressly prohibited by federal law, or by a nondisclosure agreement whose relevant text is provided to the Department, a complete copy of the documentation being submitted, which shall include the information for which trade secret protection is claimed; and (2) A redacted copy of*

*the documentation being submitted, which shall exclude the information for which  
trade secret protection is claimed.*

The JPA believes 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,

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

Michael Frost  
Executive Director

Cc: JPA Board Members

**Motor & Equipment Manufacturers Association**

1030 15th Street, NW Suite 500 East Washington, DC 20005  
Tel 202.393.6362 Fax 202.737.3742 E-mail info@mema.org



February 28, 2013

VIA E-MAIL [gcregs@dtsc.ca.gov](mailto:gcregs@dtsc.ca.gov)

**ATTN TO:**

Debbie Raphael, Director  
California Department of Toxic Substances Control

**RE: Safer Consumer Products Regulations; Revised Text of Proposed Regulations  
(Issued 29 January 2013)**

Dear Ms. Raphael:

The Motor & Equipment Manufacturers Association (MEMA) represents more than 1,000 companies that manufacture and supply motor vehicle parts for use in the light- and heavy-duty vehicle original equipment and aftermarket industries. MEMA represents its members through four affiliate associations: Automotive Aftermarket Suppliers Association (AASA); Heavy Duty Manufacturers Association (HDMA); Motor & Equipment Remanufacturers Association (MERA); and, Original Equipment Suppliers Association (OESA). These comments are in response to the Department of Toxic Substances Control (DTSC) revisions to its proposed Safer Consumer Product (SCP) regulations published on January 29, 2013 (Revised SCP Regulation) and reflect concerns of motor vehicle parts manufacturers.

As a member of the Complex Durable Goods Coalition (Coalition), MEMA supports comments submitted by the Coalition both to the original Proposed SCP Regulation (July 2012) and the recent Revised SCP Regulation (January 2013). While changes made in the Revised SCP regulation addressed some aspects of the Coalition's concerns, there are still lingering issues for motor vehicle parts manufacturers. In order to implement a workable and consistent regulatory regime, DTSC must amend its proposal to alleviate the problems and eliminate uncertainties identified by the Coalition and its members. As reflected in the Coalition comments, MEMA urges DTSC to:

- revise and clarify the meaning of specific terms/entities subject to the regulation; and,
- revise the term "Consumer Product" to exclude replacement parts.

MEMA, like our Coalition partners, welcome the DTSC revision to add the term "assembler" into the proposal as a way to meet the concerns expressed by not only the Coalition but other industry groups (see "Summary of Significant Changes in January 2013 Revised Proposed Regulations" on page 4). However, for the purposes of clarity, MEMA recommends the following changes to § 69501.1 Definitions. First, move the definition of "complex durable product" now contained in § 69503.5(c)(2) to § 69501.1(a) in the appropriate alphabetical location and renumber accordingly. Second, revise the definitions of "component" at § 69501.1(a)(23) and "importer" at § 69501.1(a)(39) to be revised as follows (*add underlined, bold text, remove strikethrough text*):

69501.1(a)(23)

"Component" means a uniquely identifiable homogeneous material, part, or piece; ~~assembly, or subassembly~~ that is a necessary or intended element of an assembled consumer product.



69501.1(a)(39)

“Importer” means a person who imports a product that is subject to the requirements of this chapter. “Importer” does not include:

- A.** a person that imports a product solely for use in that person’s workplace if that product is not sold or distributed by that person to others; **or**
- B.** **complex durable product assemblers.**

Furthermore, DTSC did not adequately address the Coalition’s request to exclude repair, refurbishment and maintenance activities from the definition of “manufacture” in the Proposed SCP Regulation. Replacement parts must be excluded. The average age of a motor vehicle on today’s roads exceeds 11 years. This extended lifetime is intentional and consumers expect motor vehicles and motor vehicle parts to last for several years, even decades. Consequently, such goods require repair, refurbishment and/or maintenance services – and need the appropriate replacement parts to ensure that these goods have a full, useful service life. In some cases, replacement parts may be associated with products that are no longer manufactured. Furthermore, in many cases, such parts must meet specific legal requirements and/or regulatory approvals or certifications.

MEMA urges DTSC to clearly exclude from this regulation replacement parts used to repair, refurbish and/or maintain complex durable goods. Therefore, DTSC must revise the definition of “consumer product” at § 69501.1(a)(24) by adding the exclusion and change the definition of “manufacture” at § 69501.1(a)(43) by clarifying what the term does *not* include (*add underlined, bold text*):

69501.1(a)(24)

**(D) “Consumer product” does not mean replacement parts used to repair, refurbish or maintain existing consumer products.**

69501.1(a)(43)

“Manufacture” means to make or produce. “Manufacture” does not include:

- (A)** acts that meet the definition of “assemble;” **or**
- (B)** **repair or refurbishment of an existing consumer product; or**
- (C)** **installation of components to an existing consumer product; or**
- (D)** **making non-material alterations to an existing consumer product.**

MEMA appreciates the opportunity to present comments on this Revised SCP Regulation. MEMA recommends that DTSC consider the specific comments in conjunction with the association’s support of the Coalition’s comments. Please do not hesitate to contact me at [lmerino@mema.org](mailto:lmerino@mema.org) for more information or questions.

Respectfully submitted,



Leigh S. Merino  
Director, Regulatory Affairs



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

February 28, 2013

Ms. Krysia Von Burg

Safer Consumer Product Alternatives Regulation Coordinator

Regulations Section

Department of Toxic Substances Control

P.O. Box 806

Sacramento, CA 95812-0806

Re: Safer Consumer Products Regulation, California Code of Regulations (Z-2012-0717-04)  
(January 2013).

Dear Ms. Von Burg:

The Natural Products Association (NPA) is submitting this letter as general comments to the Safer Consumer Product proposed regulations ("regulations") of January 29, 2013: California Code of Regulations (Z-2012-0717-04). Founded in 1936, the mission of NPA is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. We are the oldest and largest trade association in the natural products industry representing over 1,900 members accounting for approximately 10,000 retailers, manufacturers, and suppliers of natural products. NPA is concerned about the detrimental impact that the regulations as written will have on association members and the natural products industry as a whole. In addition to the comments below, NPA would like to formally support the comments submitted by the Green Chemistry Alliance. Thank you for the opportunity to comment.

NPA appreciates the adjustment regarding chemicals of concern between the last draft regulations and this iteration. Renaming the chemicals from the proposed 23 lists from

“chemicals of concern” to “candidate chemicals” is a positive development as well as the requirement that such chemicals fit an additional criterion, based on exposure risk, before being identified as a chemical of concern. However, NPA is still concerned that the regulations do not embrace the concept of a universal *de minimus* level for exemption. The current regulations propose a Practical Quantification Limit (PQL) as the threshold for an Alternatives Analysis (AA) exemption but NPA believes a general *de minimus* level of 0.1% would be workable, consistent, and protective of public health. Other regulatory authorities, such as the European Union in the EU REACH program, have found this approach to be appropriate and we urge you to consider this for these regulations as well.

NPA believes the retailer burdens under these regulations are unreasonably heavy and will lead to negative consequences. Retailers should not be identified as a responsible entity for these regulations and manufacturers of the products should not be required to list all retail outlets for their products. If retailers are identified as sellers of priority products and could be held responsible for developing AAs, we predict the vast majority of will simply refuse to sell the products. Thus, even before anyone begins an AA, the priority product may effectively disappear from many retailer shelves resulting in a *de facto* product ban. Consumers may well be denied safe, lawful, and appropriate products simply because retailers will not take on these further burdens of the law.

NPA believes the process to develop an AA is very complex, cumbersome, costly, and almost certainly beyond the financial and technical ability of many small to medium manufacturers. Again, the likely outcome is that a priority product will be withdrawn from the market, as the economic and other costs would be prohibitive. The regulations should provide a streamlined Alternatives Analysis option for small to medium-sized manufacturers or other businesses.

Overall, the regulations as currently written are so burdensome on both the Department of Toxic Substances Control (DTSC) and the regulated community that we wonder if industry can submit, and DTSC can evaluate AAs in a timely manner. This inherent problem causes the regulations to be broken, and thus ineffective, from day one. NPA would like to see DTSC start with a small pilot program. The regulations could start with one chemical of concern for one

product on a voluntary basis to give an example to both sides of how the regulations actually work.

NPA appreciates your consideration of our comments.

A handwritten signature in cursive script that reads "Cara Welch".

Cara Welch, Ph.D.

Sr. Vice President, Scientific & Regulatory Affairs

Natural Products Association

February 27, 2013

**VIA EMAIL**

Secretary Matthew Rodriquez, Chair  
Environmental Policy Council  
1001 I Street, P.O. Box 2815  
Sacramento, CA 95812  
[cepc@calepa.ca.gov](mailto:cepc@calepa.ca.gov)

RE: Comments for February 28, 2013 CEPC Meeting

Dear Secretary Rodriquez,

Orange County Business Council (“OCBC”) appreciates the opportunity to comment on the California Environmental Policy Council’s (“CEPC”) decision regarding whether to require a multimedia evaluation of the Department of Toxic Substances Control’s (“DTSC”) Safer Consumer Products Regulations (the “Regulations”).<sup>1</sup> OCBC is a section 501(c)(6) non-profit organization under the Internal Revenue Code that represents and promotes the business community. OCBC represents the business community, working with government and academia, to enhance Orange County’s economic development and prosperity and to preserve a high quality of life. Its members employ over 200,000 people within the County and over 2,000,000 people worldwide. OCBC aspires to be the voice of business for America’s sixth largest county, which has a population larger than 22 states.

California Health and Safety Code section 25252.5 requires the DTSC to coordinate the preparation of a multimedia life cycle evaluation of the Regulations and submit it to the CEPC for review. For a regulatory program as broad and complex as the one created by the Regulations, this comprehensive evaluation is a necessary safeguard to ensuring that the Regulations do not result in unexpected and significant adverse impacts. As the plain text of the statute requiring the evaluation states, a multimedia life cycle evaluation is a deliberative process that includes the “identification and evaluation of a significant adverse impact on public health or the environment, including air, water, or soil, that may result from the production, use, or disposal of a consumer product or consumer product ingredient.” Cal. Health & Safety Code § 25252.5(g). This evaluation must “be based on the best available scientific data, written comments submitted by interested persons, and information collected by [DTSC] in preparation for adopting the regulations....” Cal. Health & Safety Code § 25252.5(b). The statute also lists several possible impacts that should be examined, including: air pollutant emissions, water contamination, byproduct usage and waste disposal, and worker safety and public health. Cal. Health & Safety Code § 25252.5(b). As explained below, these potential impacts from the

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<sup>1</sup> CEPC, Notice of Public Meeting: Department of Toxic Substances Control's Safer Consumer Products Draft Regulations, Need for a Multimedia Evaluation, available at <http://www.calepa.ca.gov/cepc/2013/Feb28/Notice.pdf> (last visited Feb 26, 2013).

Regulations may well be significant and deserve to be given the analytical scrutiny envisioned by the statute that authorizes DTSC to promulgate them.

Failure to conduct a multimedia life cycle evaluation would be an abuse of discretion, contrary to law, and arbitrary and capricious. The only exception to the requirement to conduct the evaluation is “if the council, following an initial evaluation of the proposed regulation, conclusively determines that the regulation will not have any significant adverse impact on public health or the environment.” Cal. Health & Safety Code § 25252.5(f). For the reasons discussed below, this exception does not apply to the present situation.

DTSC can avoid the multimedia evaluation only where the CEPC conclusively can determine that the Regulations will not have any significant adverse impact on the public health or the environment. DTSC’s recommendation against a multimedia evaluation punts on the question of whether there will be significant adverse impacts because it states that the Regulations merely set up a “process” that does not “focus on any specific product-chemical combination.”<sup>2</sup> Similarly, the CEPC’s draft Resolution recommending no multimedia evaluation states that the “DTSC’s adoption of the proposed regulations will not affect any specific chemicals or products, and therefore will not result in any direct physical impacts to public health or the environment.”<sup>3</sup> In fact, the Regulations are not merely a process. As just one example, under the Regulations, DTSC must impose regulatory responses (including restrictions on the use of “Chemicals of Concern”) for Priority Products “when the [DTSC] determines such regulatory responses are necessary to protect the public health and/or the environment.” Draft Regulations, Sections 69506, 69506.4. The Regulations seek a fundamental restructuring in how consumer products are made, which has significant implications for manufacturing materials and waste, patterns of use and disposal, and other aspects that will affect the physical environment.

Consumer products are ubiquitous and have the potential to affect every type of media. If ever there was a regulatory program requiring multimedia evaluation, this is it. There are potential impacts from sending consumer products to landfills or recycling centers. Surface waters or publicly owned treatment works could be impacted by rinsing or cleaning consumer products with water. Off gassing from consumer products could result in impacts to indoor air quality or inhalation of chemicals in consumer products. Dermal contact with consumer products, or even young children ingesting consumer products by licking their toys, could lead to public health impacts. Disposal of consumer products may impact soil and potentially groundwater.

Just because DTSC may intend the Regulations to improve public health and the environment and may have as a goal reducing the hazard of chemicals used in consumer products does not mean the Regulations will not have a significant adverse impact on public health or the environment. The law of unintended consequences counsels a harder look—particularly for a program with such a sweeping scope and impact on the very complex web of product demand, manufacture, use and disposal. A dramatic example of the potential for significant adverse impacts is when, in an attempt to avoid the hazards of trihalomethanes, health

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<sup>2</sup> Department of Toxic Substances Control, Recommendation on Need for a Multimedia Evaluation of the Safer Consumer Products Regulations, at 2 (Feb. 2013), available at <http://www.calepa.ca.gov/cepc/2013/Feb28/Report.pdf> (last visited Feb. 26, 2013).

<sup>3</sup> California Environmental Protection Agency, Draft Resolution, at 2 (Feb. 19, 2013), available at <http://www.calepa.ca.gov/cepc/2013/Feb28/Resolution.pdf> (last visited Feb. 26, 2013).

officials in South America resisted use of chlorination of water to control a cholera outbreak, with the result that the epidemic was widespread and prolonged, resulting in many deaths.<sup>4</sup>

It is easy to think we would never make such an obvious mistake in this country, but we do not know what we do not know. While we understand water disinfection, we could be as blind as the South American health officials to significant adverse impacts caused by substituting or eliminating various chemicals in consumer products. The purpose of a multimedia evaluation is to probe for such a possibility before the damage is done. Such an evaluation is certainly warranted here. The proposed Regulations are without precedent in California and insert the government into the manufacturing business in a novel and fundamental fashion. While the program may have the best of intentions, it is important not to let laudable objectives prevent a careful examination of what negative, as well as positive, effects the program may have. A multimedia evaluation, as specified in the statute, is called for here.

Respectfully submitted,



Lucy Dunn  
President and CEO  
Orange County Business Council

LD:1

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<sup>4</sup> See F. Reiff, *The Precautionary Principle Under Fire: Detractors Continue to Challenge Chlorination as a Safe Water Solution for Developing Nations*, available at <http://www.waterandhealth.org/drinkingwater/precaution.html> (last visited Feb. 26, 2013).



February 28, 2013

**VIA EMAIL**

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

**RE: Draft Safer Consumer Products Regulations**

Dear Ms. Von Burg,

Orange County Business Council (OCBC) appreciates the opportunity to comment on the Department of Toxic Substances Control's (DTSC) revised draft Safer Consumer Products Regulations ("Regulations").<sup>1</sup> The Council represents business, working with government and academia, to enhance Orange County's economic development and prosperity and to preserve a high quality of life. Its members employ over 250,000 people within Southern California and over 2 million people worldwide.

OCBC supports the principle of "green chemistry"—that is, using lower risk chemicals where feasible and cost-effective. However, we are concerned that, as described more fully below, the proposed Regulations are based on insufficient economic analysis, focus on hypothetical harms, insufficiently protect valuable intellectual property, and fail to adequately identify regulated products. These failings should be addressed prior to the promulgation of final regulations. Further, given the Regulations' complexity and breadth, OCBC urges DTSC to undertake a meaningful and substantive review of the program's environmental impacts pursuant to the California Environmental Quality Act (CEQA).

***The Regulations are based on an incomplete and flawed economic impact analysis.*** In March 2012, DTSC released a study by Matt Kahn of UCLA entitled "Economic Analysis of California's Green Chemistry Regulations for Safer Consumer Products." Kahn's report is intended to be a prospective economic analysis of the draft Regulations, as is required by the California Administrative Procedure Act (CAPA). CAPA mandates that state agencies perform an economic analysis of the adverse impact on California business enterprises and individuals as part of the rulemaking process.

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<sup>1</sup> DTSC, Safer Consumer Products Proposed Regulations, R-2011-02 (Jan. 2013), available at <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf> (last visited Feb. 26, 2013).

OCBC asked respected economist and UC Berkley professor David Sunding to review DTSC's analysis. Professor Sunding formerly served as a senior economist at President Clinton's Council of Economic Advisers and has won several notable awards for his research, including grants from the National Science Foundation, the U.S. Environmental Protection Agency ("USEPA"), the U.S. Departments of Interior and Agriculture, and the State of California.<sup>2</sup> Professor Sunding provided the following comments on DTSC's analysis:

The Kahn analysis begins with the presumption that "[t]oday, producers, workers and California consumers know too little about the content of products." Kahn then goes on to assert that "[t]he Safer Consumer Products regulations will rectify this information gap and create incentives to encourage product makers to produce safer products." The Kahn report does not attempt to empirically estimate the costs of the regulation, but rather hypothesizes about the nature of the short and long run impacts of the program.

The Kahn report suffers from numerous deficiencies that make it unsuitable as a basis for rulemaking. These deficiencies include an overly narrow perspective on the range of industries potentially affected by the Green Chemistry regulations, and a tendency to conflate benefits and costs. This latter point is important because at several points the Kahn report cheerily asserts that even in cases where the draft regulations would result in a product being banned, such action would stimulate the development of new, superior products, and would therefore be beneficial in the long run.

Indeed, an examination of similar interventions in other industries reveals that the economic impacts of the draft Green Chemistry Regulations can be very different than assumed by Kahn. With respect to the supposed lack of information on product content, it is worth noting that in 2012 California voters soundly rejected a requirement for agricultural producers to label their products as containing genetically modified organisms. The arguments advanced by proponents of the food labeling proposition echo Kahn's almost exactly. An argument put forward by many leading economists against the measure is that such labels can overly influence consumer behavior when the underlying health risks are in fact minimal.

There is a long history in environmental economics of evaluating the costs of proposed regulations, implying that it may well be possible to do a prospective assessment of the draft Green Chemistry regulations. A good case in point is the extensive literature on the economic impact of pesticide use regulations designed to protect consumer health. The literature on pesticide regulations has demonstrated that such product regulations can indeed have significant economic costs that are borne all across the supply chain, and by consumers as well. This type of outcome is especially likely when there are no available close substitutes for the affected product.

Given the superficial and deficient nature of the Kahn analysis, it is clear that the Department does not presently possess a meaningful framework for conducting economic analysis on a product-by-product basis. It would not be appropriate to apply the Kahn

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<sup>2</sup> Professor Sunding's biography is provided as Appendix A.

approach in a product-specific context. Between now and product-specific evaluations, it would be useful for the Department to develop an appropriate framework for economic analysis on a product-specific basis.

As DTSC is no doubt aware, the economic costs of the Regulations are projected to be enormous. In-depth, sound and balanced economic impact analysis is feasible and is called for as the program has the potential to place an enormous economic burden on California businesses. The Regulations currently are not supported by such an analysis. This is particularly troubling given that, as discussed below, the benefits of the program may be minimal, and the potential for harm to intellectual property is real.

**The Regulations unreasonably focus on hypothetical and uncertain future harm, imposing significant burdens without ensuring greater protection of the public health.** The thrust of the Regulations is to eliminate use of a substance identified as a Chemical of Concern (“COC”) in a Priority Product. However, replacement or elimination of a chemical provides no significant benefit if it in fact posed no significant risk. The Regulations provide that products chosen as “Priority Products” need to have a “potential ... exposure to the Candidate Chemical(s) in the product” and have the “potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.” Section 69503.2(a).<sup>3</sup> “Potential” is defined to mean “that the phenomenon described is reasonably foreseeable based on reliable information.” Section 69501.1(a)(51)(A). “Contribute to” and “significant and widespread adverse impacts” are not defined and so are subjective.

Under this test, products with a mere potential to create an exposure can be targeted and subject to the intense scrutiny of an alternatives analysis, even if that potential exposure would pose no cognizable risk. For example, DTSC revised the last Regulations draft to virtually eliminate a provision exempting Priority Products with *de minimis* COC levels from the alternatives analysis (“AA”) requirement; as currently drafted, Priority Products are eligible for the exemption only if it is not possible to quantify the amount of the COC present in the Priority Product and the chemical was not intentionally added. Sections 69501.1(a)(52) and 69505.3(a)(4). If one can quantify the concentration of the chemical—no matter how low—an elaborate and costly AA is required. In effect, the Regulations are directed at perceived and not necessarily real risks. The costs imposed by the Regulations are far too great in comparison to the speculative benefits of this approach that would require an extensive alternatives analysis and the costs of reformulation even where risks to human health and the environment are negligible.

**The Regulations fail to protect valuable trade secrets, placing regulated parties seeking to comply at significant risk of losing their competitive edge in the marketplace.** The Regulations compel manufacturers of consumer products to disclose trade secret information to DTSC, presenting potential risks to valuable company information. OCBC urges DTSC to revise the trade secrets provisions to ensure the protection of regulated parties’ proprietary and valuable material. As currently drafted, the Regulations require companies to provide DTSC with highly sensitive confidential information that may be vital to the competitiveness of the company. Such information includes:

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<sup>3</sup> All citations are to the proposed Regulations unless otherwise noted.

- disclosure of the functional role that the COC plays in Priority Products, Section 69505.5(a)(2);
- disclosure of information regarding potential alternatives that may also reveal critical competitive information, Section 69505.7(j)(2);
- disclosure of the company's customer list, including contact information – information that is an important part of a company's goodwill value, which in turn is a significant percentage of a company's assets, Section 69505.7(d)(3);
- disclosure of retail outlets to which the company has simply offered its product, Section 69505.7(d)(4); and
- disclosure of products in which the COC is a component, Section 69505.7(e)(2).

Further, parties seeking trade secret protection from DTSC for information contained in AA reports must supply DTSC with additional information that is itself confidential. For example, to secure trade secret protection, parties must provide DTSC with the estimated value of the information to the person and the person's competitors and an explanation as to why the chemical identity is not readily discoverable through reverse engineering. Section 69509(a).

It is not apparent that DTSC has a system that will ensure the protection of such highly sensitive information. Similar information is provided to the USEPA under the Toxic Substances Control Act ("TSCA"), but that agency has a rigorous process for submission, processing, distribution and filing to ensure that information claimed as confidential is not disclosed. This is bolstered by provisions in TSCA making unauthorized disclosure a criminal act with substantial monetary penalties. *See* TSCA Section 14, 15 U.S.C. Section 2613. The final Regulations should spell out a clear and effective procedure for the protection of confidential information by DTSC, including penalties for any person who discloses such information.

DTSC's economic impact analysis downplays the risk of the revelation of trade secrets. *See* Economic Impact Analysis at 15. This is a fundamental failing of the economic analysis and reflects no appreciation of the potential harm to U.S. companies and the country's economic competitiveness should serious breaches of such trade secret information occur, including through industrial espionage such as recently reported in the news media.<sup>4</sup> Given such activities, the risk of trade secret information being acquired by competitors is at least as probable as some of the hypothetical chemical harms being addressed by the Regulations. Because the Regulations require submission of information that would have high value in a competitor's (or another country's) hands, strict measures are necessary to prevent unauthorized disclosure. Trade secret protection and the potential risk to intellectual property posed by the Regulations are key concerns DTSC should address prior to finalizing the Regulations.

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<sup>4</sup> *See, e.g.,* D. Hall, The Morning Ledger: U.S. Takes Aim at Corporate Espionage, Wall Street Journal CFO Journal (Feb. 21, 2013), available at <http://blogs.wsj.com/cfo/2013/02/21/the-morning-ledger-u-s-takes-aim-at-corporate-espionage/> (last visited Feb. 26, 2013).

**The Regulations' "list of lists" approach is fatally flawed and prevents meaningful review and comment by the public and potentially regulated parties.** Despite taking over four years to develop the Regulations, DTSC has still failed to specify the chemicals that it intends to include on its "Candidate Chemicals" list. Section 69502.2. The "list of lists" approach taken by DTSC is exceedingly confusing and greatly lacking in transparency. Despite provision of internet links by DTSC,<sup>5</sup> it is extremely difficult to cobble together a single list of chemicals. Some of the links are broken. Others link not to the list, but to a page from which the list can be accessed—although how to do so is not always clear. In some cases, such as "Chemicals classified as carcinogens, mutagens, and/or reproductive toxicants Categories 1A and 1B in Annex VI to Regulation (European Commission) 1272/2008," the relevant chemicals must be laboriously weeded out from a very long list of chemicals. Section 69502.2(a)(1)(B). Even after locating all of the lists, creating a consolidated list is challenging because of different chemical nomenclatures used by the various entities. And even if one has the many hours and chemical expertise to work through all of this, in the end one only has a list of chemicals from which DTSC may select Candidate Chemicals, not a definitive list that provides clear notice of what chemicals DTSC will target.

The Regulations require DTSC to create an "informational list" of the Candidate Chemicals within 30 days after the effective date of the regulations. Section 69502.3(a). If DTSC can create such a consolidated list, it is contrary to common sense and fairness that DTSC would do so only after the Regulations take effect. To promote transparency and prevent legal error, DTSC should spell out which chemicals it will list. In fact, additions to that initial list are to be accomplished through a notice and comment process. See Section 69502.3(c), (d). The exact chemicals for the initial list should go through the same process, before the Regulations are finalized. The failure to do so is a foundational problem that causes serious complications, including preventing meaningful review by the public as well as obstructing credible economic and environmental review of the program before its enactment. The potential effects of the Regulations cannot be accurately assessed without knowing what chemicals will actually be involved.

**The DTSC should prepare an Environmental Impact Report ("EIR") under CEQA, a necessary safeguard for the public and the environment.** DTSC previously indicated that it was considering filing a Notice of Exemption ("NOE") and thus avoiding the review and analysis required by an EIR under CEQA.<sup>6</sup> According to the draft NOE, DTSC determined

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<sup>5</sup> See DTSC, *Proposed Chemicals Lists* (Aug. 2012), available at <http://dtsc.ca.gov/LawsRegsPolicies/Regs/upload/COC-lists-weblinks2.pdf> (last visited February 25, 2013).

<sup>6</sup> The draft NOE was issued by DTSC along with the July 2012 draft of the Regulations. See DTSC, *California Environmental Quality Act Notice of Exemption* (July 26, 2012), available at <http://dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-CEQA-NOE-7-26-12.pdf> (last visited February 26, 2013). DTSC also stated that it believed the Regulations qualified for the CEQA exemption in California Public Resources Code section 21080(b) in the notice of the draft regulations in July 2012. See DTSC, *45-Day Public Notice and Comment Period* (July 23, 2012), available at <http://dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Public-Notice-7-23-2012.pdf> (last visited February 26, 2013). However, this section exempts from CEQA rates, tolls or other charges by public agencies for specific purchases. DTSC should provide further information about why the Regulations are exempted under this section.

“[w]ith certainty, no possibility of a significant effect on the environment” under title 14 California Code of Regulations, Section 15061(b)(3). However, DTSC later states in the draft NOE that “analyzing whether there could be a significant effect on the environment as a result of requiring an alternatives analysis for any of the approximately 1,200 COCs in any of tens or hundreds of thousands of consumer products is incredibly speculative.” DTSC then claims that because of this uncertainty, it need not perform further analysis, citing Title 14, California Code of Regulations, Section 15145, which requires a “thorough investigation” prior to terminating the discussion. DTSC is essentially using a problem it created—the uncertainty surrounding the identification of Candidate Chemicals—to avoid CEQA’s requirements. DTSC can and should do the work needed to determine which chemicals and products will be affected before implementation. DTSC can then actually perform a “thorough investigation” into the Regulations’ impacts.

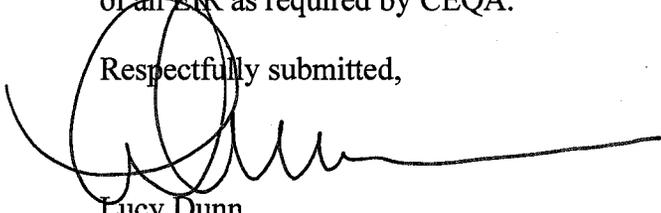
DTSC’s draft NOE claims that the Regulations are a process consisting of “intellectual evaluation and analysis only” and as such will not create a physical change in the environment. This is inaccurate. The program created by the Regulations requires far more than just detached analysis. As just one example, under the Regulations, DTSC must impose regulatory responses (including restrictions on usage of Chemicals of Concern) for Priority Products “when the [DTSC] determines such regulatory responses are necessary to protect the public health and/or the environment.” Sections 69506, 69506.4. Clearly, the Regulations are not just a process. They seek a fundamental restructuring in how consumer products are made, which has significant implications for manufacturing materials and waste, patterns of use and disposal, and other aspects that will affect the physical environment.

The purpose of CEQA and of programmatic EIRs is to think through, to the extent possible, the implications of regulations for the environment, before those regulations are put in place. Expert opinion on the Regulations’ significant effects should be developed and placed in the record before implementation of the Regulations. Despite DTSC’s assurances that it will continue to undertake CEQA evaluation, meaningful review cannot wait until after implementation, when there will be an incentive not to unwind or question the Regulations already in operation.

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For the reasons given, OCBC requests that DTSC undertake additional analysis before promulgating final regulations, including a robust economic impact analysis as required by CAPA; selection, with notice and comment, of the initial Candidate Chemicals; and development of an EIR as required by CEQA.

Respectfully submitted,



Lucy Dunn  
President and CEO  
Orange County Business Council  
LD:BS:ld

## **Appendix A – Biography of Professor David Sunding**

David Sunding is the Thomas J. Graff Professor in the College of Natural Resources at UC Berkeley. His research concerns environmental and resource economics, regulation, technological change, applied econometrics, risk and public finance. Prof. Sunding teaches courses in natural resource economics, water resources, and law and economics.

For the 2010-2011 academic year, he was a Visiting Professor in the Woods Institute of the Environment at Stanford University.

Prof. Sunding has won several important awards for his research, including grants from the National Science Foundation, US Environmental Protection Agency, the US Departments of the Interior and Agriculture, the State of California, and private foundations. He has served on panels of the National Research Council and the USEPA Science Advisory Board. He has advised federal and state government agencies on the development of policies and regulations in the area of natural resources and the environment.

Prof. Sunding earned his Ph.D. from UC Berkeley in 1989. Prior to his current position, he served as a senior economist at President Clinton's Council of Economic Advisers. He is a member of the American Economic Association, the Association of Environmental and Resource Economists, the Econometric Society, and the American Law and Economics Association.



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February 27, 2013

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

Deborah O. Raphael, Director  
California Department of Toxic Substances Control  
1001 I Street  
Sacramento, CA 95814-2828

**re: comments on Proposed Safer Consumer Products Regulations**

Dear Ms. Raphael:

I am pleased to submit the comments of the Outdoor Power Equipment Institute on the revised proposed Safer Consumer Products Regulations (Regulations) released by the DTSC on January 29, 2013.

The Outdoor Power Equipment Institute is the major international trade association representing the manufacturers and their suppliers of consumer and commercial outdoor power equipment such as lawnmowers, garden tractors, utility vehicles, trimmers, edgers, chain saws, snow throwers, tillers, leaf blowers and other related products. The products manufactured by this industry are “complex durable goods”, composed of 100 or more manufactured components, with a service life of several years, and typically not consumed, destroyed, or discarded after a single use.

The following are the OPEI’s primary concerns with the proposed regulations.

**Service parts for products that ceased to be manufactured prior to the date the product is listed as a Priority Product (Section 69501.1 (24) (B)) should be exempted from the Regulations**

Complex durable goods generally can have a service life from several years to decades, and rely on the availability of service parts for repair. In order to protect the investment of the consumer in a complex durable good, service parts for “historic products” must be exempted from the regulations just as the products they service, which ceased to be manufactured prior to listing as a Priority Product. There are many important considerations which support an explicit exemption for service parts, which include: they are often manufactured and distributed in small quantities, it is not economically feasible to develop and produce new service parts, they provide consumers with the benefit of extending the lifetime of a product at an equivalent level of performance and



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quality, and finally it supports the broader environmental benefits of product reuse and refurbishment.

Revise Section 69501.1 (24) to add new (D) as follows:

“Consumer product” or “Product” does not mean a service part, regardless of when it is manufactured, for a product that ceased to be manufactured prior to the date the product is listed as a Priority Product.

**The practicability of chemical analysis should be taken into account in order to enable effective control of consumer products on the market (Section 69501.1 (23) (A))**

The broad definition of “Component” implies difficulties in analysis for complex durable goods. For a manufacturer of a part it is possible to control the raw materials used for production. On this level any homogeneous material used in the manufacturing process is readily available in quantities that enable an accurate analysis. The task of the analysis becomes much more complex, if the manufacturer of the consumer product uses subassemblies from another manufacturer. The detection of a “Chemical of Concern” in a subassembly depends on the sample preparation, the measurement method and equipment as well as the skill of the laboratory personnel, since the homogeneous material may only be available in very small quantities. An accurate definition of the material for analysis is crucial for sensitive detection of “Chemicals of Concern” and for reproducible results from different laboratories. Since the basis for a maximum permissible value has to be defined unambiguously, it should be connected to the component listed as a “Priority Product”.

Revise Section 65501.1 (23) (A) as follows:

“Component” means a uniquely identifiable homogeneous material, part, piece, assembly, or subassembly that is a necessary or intended element of a consumer product. A quantitation limit or maximum permissible value of a chemical of concern is always based on the maximum concentration value of the chemical in component listed as priority product.

**Compliance time frames are inadequate**

In general, the time allowances for compliance throughout this proposed regulation are insufficient for manufacturers of complex durable goods. Detailed recommendations for extensions were supplied in the Complex Durable Goods Coalition comments to the previous draft, but in large part were not implemented. Many of the products manufactured by the outdoor power equipment industry are developed and manufactured based on a model year process, with particular demands for extended lead times of five years or more. The various stages of the design process all require extended time frames as recommended in the comments of the



OUTDOOR POWER EQUIPMENT  
INSTITUTE

Complex Durable Goods Coalition to the previous draft, including research and development, testing, prototyping, validation and approval from various regulatory agencies. Additionally, manufacturers of complex durable goods also rely on complex supply chains, which serve as partners in design and material selection, but add to the time necessary to comply with the Alternative Analysis requirements specified. It is also noteworthy, as an example, that in the EU's REACH regulation the time allowed for one of the first regulated substances, phthalate plasticizers, is over six years from listing as a SVHC until the sunset date.<sup>i</sup>

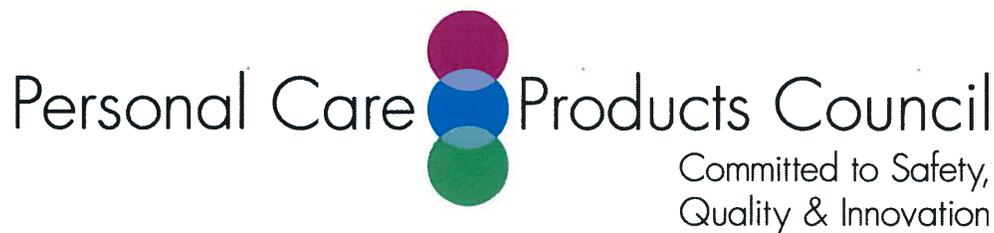
We appreciate the opportunity to provide comments on this regulation.

Best regards,

Daniel J. Mustico  
Director, Industry Affairs  
[dmustico@opei.org](mailto:dmustico@opei.org)

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<sup>i</sup> The phthalate plasticizers bis (2-ethylhexyl) phthalate (DEHP), benzylbutylphthalate (BBP) and dibutylphthalate (DBP) were among the first substances placed on the "Substance of Very High Concern" (SVHC) list (the REACH equivalent of a "Priority Chemical") in December 2008. They were included in the list of substances that are subject to authorization (Annex XIV) on February 17, 2011 and the deadline for authorization requests will be on August 21, 2013. The sunset date will be on February 21, 2015. After this date the substances may only be used if they were authorized or an application was made on time, but the final decision by the European Chemical Agency (ECHA) has not yet been taken.



February 28, 2013

**By Electronic Mail**

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

**RE: "Revised" Proposed Safer Consumer Products Regulations**

Dear Ms. Von Burg:

The Personal Care Products Council (Council)<sup>1</sup> is pleased to submit the following comments on California's Safer Consumer Products proposed regulations that were developed by the Department of Toxic Substances Control (DTSC) and publicly released on January 29, 2013. Our member companies are involved in the manufacture and distribution of over-the-counter (OTC) drug products, cosmetics, toiletries, fragrances, and ingredients in California and throughout the United States, and therefore have a strong interest in the scope and applicability of these regulations.

**INTRODUCTION**

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

Although the Council has continuing concerns about the Safer Consumer Products regulation, it is evident from the recently released "revised" proposed regulation that DTSC has addressed some of our

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

previous objections and made important modifications. Therefore, in an effort to preserve the positive changes and ameliorate the negative changes to the regulation, the Council respectfully submits the following comments for your consideration:

### **Positive Revisions**

- **Certified Assessors/Accreditation Bodies.** One of the Council's primary concerns with the proposed regulation was the provision relating to Certified Assessors and Accreditation Bodies. In its revised regulation, DTSC has eliminated this problematic provision in its entirety.
- **Administrative Procedure Act.** Language has been added that makes it clear that the Priority Products list will be established and updated through a separate Administrative Procedure Act (APA) rulemaking process. This is a positive addition.
- **Exemption.** An applicability exemption has been added for products regulated by other laws that provide equivalent or greater protections in connection with the same public health and environmental impacts and/or exposure pathways that are addressed by the regulations. This exemption, previously considered as just one factor of many in prioritizing chemical/product combinations, is now an upfront exemption.
  - While this change is generally positive, the Council recommends creating some parameters around this provision to clarify how and when it will be applied. Without such parameters, the utility of the exemption will be severely limited, and DTSC will have unfettered discretion to determine when and whether the exemption applies to a product. The Council believes that regulatory duplication for any product should be an upfront and straightforward question in the applicability stage of the regulation – is the potential health or environmental impact from the chemical in the product regulated by another regulatory agency or not? If it is regulated by another agency, then it should not be in the scope of the proposed regulation.
  - Likewise, the previous version of the proposed regulation included language that exempted products in the supply chain of exempted products. This language was deleted, suggesting that DTSC believes that it can select a priority product-chemical combination upstream in an exempted product supply chain. DTSC does not have this authority and such action would supersede the regulatory scope of other agencies, which is prohibited by the underlying green chemistry statute.

- **Harmonization.** A provision has been added that explicitly states nothing in the regulations authorizes DTSC to supersede the requirements of any other California, state or federal regulatory program. The Council applauds this inclusion.
  - The Council notes, however, that the Harmonization language diverges from to the underlying green chemistry statute, SB 509 (Simitian, 2008), which states: *“This article does not authorize the department to supersede the regulatory authority of any other department or agency”*. The revised proposed regulations speaks to *“superseding the requirements”* of another program. This is quite different, and the Council recommends using the statutory language to avoid confusion and ensure faithfulness to the law.
  - Likewise, the revised regulation does not acknowledge the second prohibition in the statute, which states that DTSC *“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 should be also included in the proposed regulation.
- **“Candidate Chemicals” List.** The term “Chemicals of Concern” was being used to describe the initial list of chemicals to be considered when prioritizing product and chemical combinations. The term had a negative connotation and would have resulted in a *de facto* “black list” of chemicals. By changing the term “Chemicals of Concern” to “Candidate Chemicals”, DTSC acknowledged and addressed this concern. Now, only those Candidate Chemicals that are the basis for a product-chemical combination being listed as a Priority Product will be designated Chemicals of Concern.

In addition to these important changes, DTSC made several other modifications to the proposed regulation that the Council also recognizes as positive. Nevertheless, we believe that additional changes are warranted to make the proposed regulations more effective and less burdensome for the regulated community. As such, the Council offers the following comments in the hopes that DTSC will consider them and make the suggested changes before issuing the final regulation.

#### **Negative Revisions and Recommended Changes**

The Council has identified four primary problems with the revised proposed regulation that are critically important to our industry:

1. **Alternatives Analysis (AA) Threshold.** Without question, the single biggest problem with the revised proposed regulation is the change DTSC made to the AA Threshold. DTSC has defined the threshold as the Practical Quantification Limit (PQL) for a Chemical of Concern that is

present in a Priority Product solely as a contaminant. In essence, DTSC has eliminated any semblance of a reasonable threshold “trigger”, and replaced it with a threshold that provides no benefit or certainty to responsible entities. First, PQL is for all practical purposes equivalent to detection. Second, it is far too subjective; what constitutes “routine laboratory operating procedures” for one company may differ dramatically from what it means to another company. Third, the threshold trigger only applies to contaminants, not ingredients. As a result, once any contaminant (i.e., ingredient not intentionally added to a product by design) is detected, it has exceeded the trigger.

**Recommendation:** As we have recommended with each version of the regulation, DTSC should align its AA threshold trigger with other government authorities that have set a 0.1% threshold. A practical default AA threshold would provide certainty and predictability to the regulated community allowing them to fully understand their compliance responsibilities. Likewise, setting a uniform threshold amount for all chemicals at 0.1% would make the proposed regulations consistent with a majority of state, federal and international regulations, including the European Union’s R.E.A.C.H. framework, which employs a 0.1% by weight *de minimis* threshold for reporting as well as the European Cosmetics Directive which includes a 0.1% *de minimis* level for over 1,300 carcinogens and reproductive toxicants.

In the event that DTSC continues to reject our call for a 0.1% AA threshold, we would recommend reverting to a .01% for all carcinogens, mutagens, and reproductive toxicants, with all remaining chemicals subject to a default 0.1% by weight threshold. This is critical in order for responsible entities to have a clear understanding of how to comply with the regulations as the PQL approach will only create inconsistency with already established regulatory limits and uncertainty within the regulated community as to how they will comply with the regulation.

- 2. Public Notice and Comment for AAs.** With the elimination of Article 8 relating to Certified Assessors/Accreditation Bodies, DTSC has created a requirement that all Preliminary AAs be made available for public comment. Responsible Entities would be required to review, summarize, and respond to public comments on the Preliminary AA as part of its Final AA. This unfortunate provision would result in an onerous and cumbersome process that demands more time and effort with no additional benefits.

The Council understands that DTSC is looking for some form of “quality control” of the AA reports, given the elimination of the certified assessor requirement. Quality control, however, is already assured without the need for public notice and comment. First, DTSC is developing and

will publish an AA guidance document following the promulgation of these regulations. This not only provides direction to responsible entities preparing AAs, but will allow DTSC to determine rather easily whether a responsible entity has complied with the process identified in the guidance. Likewise, DTSC has a host of regulatory responses at its disposal to ensure that AAs are properly conducted, and that responsible entities are sufficiently motivated to comply. There is no need for DTSC to add another layer of “oversight” to this already complex process.

Nevertheless, assuming DTSC intends to pursue some form of additional “quality control” over the AA process, the Council offers two potential options, discussed below.

**Recommendation:** **Option 1:** The preferred option is for DTSC staff to take responsibility for reviewing the alternative assessments because they are the ones that are bound to maintain business confidentiality. Industry, as before, would willingly provide free, in-depth training to DTSC staff in order to ensure the staff had the knowledge and understanding to conduct an AA review. This would have the advantage of improving the depth of the agency’s internal expertise, provide the kind of quality control DTSC seeks, and insulate the agency from accusations of “outsourcing” its non-delegable regulatory responsibilities.

**Option 2.** As a second option, DTSC could allow for public notice and comment, but permit the responsible entity to dismiss non-science based comments it deems non-germane – meaning the responsible entity would not have to issue a formal response to such comments in its Final AA. By setting such parameters, or standards, around the types of comments a responsible entity must respond to, DTSC would ensure a science-based review process that would address its quality control concerns for AA reports.<sup>2</sup>

- 3. Demonstrating Safety.** The revised proposed regulation still is unclear about whether there is an opportunity for a responsible entity to demonstrate the safety of a priority product as a compliance option to satisfy the AA requirements, such that if the safety of the priority product is demonstrated there is no need to designate a product as a Priority Product and thus no need to go deeper into the alternatives assessment.

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<sup>2</sup> In the same way, the U.S. Food & Drug Administration does not allow any member of the public to weigh in on clinical trials that are part of the drug approval process. Rather, such review is limited to a scientific panel of experts.

**Recommendation:** Create an upfront compliance option that would allow a responsible entity to demonstrate the safety of its product *before* it is listed as a Priority Product under the regulation, thus allowing a responsible entity to avoid conducting the requirements of an AA. This could be accomplished through the rulemaking pursuant to the Administrative Procedures Act, however regulation should clearly state that this will be an opportunity for responsible entities to demonstrate that a candidate chemical-product combination is safe as it is used. This would eliminate the need to designate a product as a priority product in the case where safety of the product-chemical combination is adequately substantiated. As currently proposed there is no assurance to responsible entities that this opportunity exists.

4. **Trade Secrets.** The Council supports the inclusion of protections for confidential business information and trade secret, as these issues are critically important for businesses. Certain aspects of the trade secret provision are similar to the previous version of the proposed regulation, with both incorporating the protections found in the *California Uniform Trade Secrets Act*. Other aspects, however, are different, such as requiring a company that is seeking trade secret protection – i.e., seeking to “mask” the identity of the chemical – to prove that a patent application is pending for the chemical or its contemplated use in the product. Moreover, DTSC will only mask the chemical identity and keep it confidential in published materials until the patent application is granted or denied. Then it will be made public. This is problematic at best and must be addressed.

**Recommendation:** As noted above, the Council is particularly concerned about the proposed hazard trait submissions, which includes the disclosure of chemical identity. The revised proposed regulation states that chemical identity that is the subject of a hazard trait submission may only be “temporarily masked”, or claimed as trade secret, when the chemical is a considered or proposed alternative *and* when a patent application is pending for the chemical or its use in the product.

Unfortunately, this requirement improperly combines two distinct forms of intellectual property protection in a manner which seriously erodes existing statutory and common law property rights currently granted to owners of trade secrets.

Under both the state and federal statutory law, an entity may claim as trade secret any information that generally (1) is used in one’s business (2) has economic value or provides an economic advantage (3) is not generally known, and (4) is not readily ascertainable by others. Trade secrets will last for as long as they remain undisclosed to the public. Patents, on the other

hand, require something to be (1) novel, (2) useful, and (3) non-obvious, requirements that a chemical or its use in a mixture may not meet.

A company will make a strategic business decision as to whether to seek trade secret protection, which lasts indefinitely (or until the information becomes public), or file for patent protection, which provides exclusive rights to the patent holder for 20 years. A company may not elect to file a patent on every discovery that provides them with a competitive advantage. In many cases, particularly where the discovery or invention is a product formulation that cannot readily be analyzed or which is not discernible by inspection, an entity will choose trade secret protection over prospective patent protection, due to the potentially unlimited time frame for maintaining the economic advantage obtained from the trade secret.

Yet DTSC inappropriately conflates these two concepts, resulting in the following problems:

1. The regulation could force entities to either waive their property rights with respect to their existing trade secrets, or to take on the considerable expense of preparing, filing, prosecuting and maintaining patent protection over all of their inventions and discoveries, in order to continue to avail itself of its statutory and common law rights governing trade secret protection.
2. In its revised proposed regulation, DTSC states that any trade secret will lapse when the patent is granted or denied. But in fact, those trade secrets would lapse once the patent application is published (i.e. publicly disclosed), which is often years before a patent is actually granted or denied.
3. There is also the problem with foreign competitors gaining access to critically important intellectual property. A U.S. patent, for example, would not prevent Chinese companies from using the patented information to their own advantage. Likewise, the proposed regulation would place U.S. companies in the untenable position of having to disclose their most economically valuable trade secret product formulations in a manner which ultimately would place those trade secrets in the hands of foreign competitors. At a time when the U.S. government is aggressively implementing procedures to prevent other countries from stealing billions of dollars' worth of intellectual property from U.S. businesses,<sup>3</sup> DTSC's revised proposed regulation could actually make our IP more vulnerable.

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<sup>3</sup> Congress recently enacted the "Theft of Trade Secrets Clarification Act" and the "Foreign and Economic Espionage Penalty Enhancement Act of 2012", and, on February 20, 2013, the White House released the Administration's "Strategy on Mitigating the Theft of U.S. Trade Secrets which recognizes the crucial role of trade

For the forgoing reasons, the Council therefore urges DTSC to revise this provision to ensure a sensible, and legally defensible, final rule.

### **Additional Concerns**

In addition to the four primary concerns/recommended changes set forth above, the Council would like to highlight the following additional problems with the regulations that merit removal or modification:

- DTSC revised the list of Candidate Chemicals to include additional chemicals, adding to the already robust list of chemicals. The list, which was previously described as 1,200 chemicals, has now been expanded to include chemicals classified by the European Union as Category 1 respiratory sensitizers and additional pollutants identified under the Clean Water Act's 303(d) list.
- Excessive notice requirements remain in place under the regulation, some with additional information burdens such as identifying the raw material sourcing of chemicals and periodic reports on the development and introduction of alternative products into the marketplace.
- DTSC has added economic impact analysis requirements, ostensibly for the benefit of industry, requiring the responsible entity to analyze public health costs and costs to local government and others in managing solid waste, among other public goods. This is both excessively burdensome and unnecessary.
- There is a mandatory requirement to provide an upfront financial guarantee, including providing compensation to retailers, where "end-of-life management" is the selected regulatory response. While this burden is lessened if the program is administered by a nonprofit third party, the new annual stakeholder public comment and consultation requirements will subject the manufacturer to annual and unknown revisions to the program.
- DTSC has substituted the word "impact" with "effects" throughout the regulation, the word "ability" (to cause adverse impacts) with "potential", and eliminated risk-based wording in the Prioritization Key Factors, all in an effort to focus on hazard and presence as the dominant triggers for identifying a Priority Product.

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secrets in the U.S. economy and sets out a means for improved coordination within the U.S. government to protect them.

Ms. Krysia Von Burg  
February 28, 2013  
Page 9 of 9

## CONCLUSION

While the revised proposed regulation may ultimately provide some benefit to public health and the environment, they also create regulatory inconsistencies and impose unnecessary costs and burdens upon industry. We believe that it is critical that DTSC construct a program that is workable from the onset, with a narrowly drawn scope and requirements that are not cost-prohibitive. To that end, the Council urges you to consider our comments to avoid creating barriers to innovation, detrimentally impacting the California and U.S. economy, and ultimately failing to improve protection of public health and the environment.

Sincerely,

A handwritten signature in blue ink, appearing to read "Thomas F. Myers", with a long, sweeping underline.

Thomas F. Myers  
Associate General Counsel



## **Plastic Pipe and Fittings Association**

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**Ms. Krysia Von Burg**  
**Section Department of Toxic**  
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Ms. Von Burg,

The Plastic Pipe and Fittings Association (PPFA) would like to thank the California DTSC for the opportunity to comment on the proposed regulations to implement Assembly Bill 1879, as codified in §§25251-25257.1 of the California Health and Safety Code. We believe that health, safety, and environmental protection policies for products are most effective when they incorporate risk-based priorities, Life Cycle Analysis, and cost effective decision-making.

Even with the significant modifications in the new draft, PPFA is still concerned that the complexity, scope, subjective sometimes confusing nature, and burden of the proposed regulations will undermine the statutory objectives of minimizing consumer exposure to products that may pose risks of harm and promoting innovation. The current legislative draft is to say the least, a difficult read.

PPFA understands that many in the industry have input considerable effort to suggest meaningful, practical, and legally defensible regulatory alternatives, and that the current proposal still represents unscientific and over-burdensome regulation if a product is selected.

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

Although DTSC has estimated that some 1,200 substances will be covered by the

regulation, the American Chemistry Council (ACC) had previously estimated that the regulation would affect at least 4,000, if not more. This would strain both industry and the State of California.

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

In some cases, these lists were developed for purposes far removed from consumer product regulation. In general, the lists are not relevant to the levels of chemical exposure in consumer products. More to the point, consumer apprehension will certainly lead to de-selection – and for all the wrong reasons.

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

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

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

PPFA asks the DTSC to propose a much simple program based on LCA and abandon the incorrect pathway of materials and chemical lists for de-selection of products.

**SPECIFIC PPFA COMMENTS ON THE PROPOSED REGULATIONS  
POST-HEARING CHANGES SAFER CONSUMER PRODUCTS (SCP)  
(R-2011-02)**

Section “(20) (B) “Molecular identity”

*This section is very confusing. Nearly the entire list of parameters is not relevant. Items 1, 2, 3, 5, 7, 8, 11, 12, 13, 14, are not functions of a materials molecular makeup, but mostly, morphology or particle size and shape. As an example, steel plates are not considered flammable or reactive, but steel wool is. Beach sand is not carcinogenic, but fine silica particles of a particular morphology can be.*

*Recommend deleting the section.*

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(26) (A) “Contaminate” .....

*This lengthy section regarding components of a product is lacking in minimum quantities that would determine a detectable “trace” from a true “contaminate” which would be worthy of inclusion. The federal Occupational Safety and Health Administration (OSHA), the Globally Harmonized System for Classification and Labeling (GHS), and the European Union’s REACH standard apply a risk-based de minimis threshold of 1% for hazardous chemicals, and 0.1% for carcinogens, mutagens, and reproductive toxins. We suggest the draft include some limit, or a “contaminate” could be in parts-per-billion or even trillion.*

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(26) (D) “Recycled material” means a material that has been ~~separated from a waste stream~~ collected for the purpose of recycling the material as a feedstock for use in a new product.

*Recommend editing the section. Products can be and are collected for use as recycled feedstock without entering the waste stream.*

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(29) “Economically feasible” means that an alternative product or replacement chemical does not significantly reduce the manufacturer’s operating margin.

*Recommend deleting definition, how does one know what “significantly reduce margins” is? How does one forecast pricing for a product or a material that may become increasingly sought after?*

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(35) “Functionally acceptable” means that an alternative product meets both of the following requirements;

(A) The product complies with all applicable legal requirements; and

(B) The product performs the functions of the original product sufficiently well that consumers can be reasonably anticipated to accept the product in the marketplace.

*Part (B) is essentially, impossible to predict. Remember “New Coke” as an example. Multi-million dollar products that show promise often fail to satisfy the marketplace.*

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(38) “Import”

*The definition of “import” is made unclear by the new second sentence, “import’ does not include ordering a product manufactured outside of the United States if the product is ordered from a person located in the United States.”*

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69502.2. DELETE (B), (C), (G), (H) and (I)

*We recommend not being dependent on European data for California or US regulations. While there may be clear pathways for US manufacturers to provide input to US chemical programs, I don’t believe we could provide useful input to EU programs. There could be intentional or unintentional impacts from EU lists on American manufacturing. Delete these lists.*

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69503.2 (and elsewhere) “exposure”

*The term “exposure” will need to be defined further for the regulation. Morphology and particle size, among other factors, will need to be considered, not just the chemical make-up. One can be directly exposed to a material in one form, such as a glass or a solid, and have no intake or negative impact, where a finely divided form of the same material minor contact could be quite harmful. In short, the chemical make-up of an item is not sufficient to declare an “exposure” to it.*

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69503.3 Adverse Impact and Exposure Factors.

*The section (A) “Sensitive subpopulations” and following similar language is troublesome, and should be deleted. How does one know what a sensitive subpopulation is or is impacted by? Certainly, there are a subpopulation of the population of California*

*that can be seriously impacted by allergies to very common, and generally safe chemicals and products, such as latex, nuts, and other foods. This is no reason to ban/replace materials from the State, nor could it be somehow enforced.*

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(H) “degradation products”

*A great span of chemical and products via the application of heat, electrical arc or fire, will undergo degradation to harmful, even carcinogenetic products. This includes wood, plastics, solvents, fabrics, coatings, etc. Recommend deleting this section, or you may have to find a safer replacement product for wood.*

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February 28, 2013

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

**Subject: Safer Consumer Products Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (January 2013)**

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

Dear Ms. Von Burg:

On behalf of Plumbing Manufacturers International (PMI), we are submitting the following comments in response to the Department of Toxic Substances Control's ("Department" or "DTSC") revised proposed Safer Consumer Products Regulation ("regulation") of January 2013. Additionally, PMI has filed comments to all prior iterations of the regulations, including the July 2012 proposal, which we incorporate here by reference.

PMI is the leading national and technical trade association of plumbing products manufacturers in the United States. Our 31 manufacturers and allied members include many of the well-known companies selling plumbing products in the United States for decades. Our collective group of manufacturers is responsible for at least 90% of all the fixtures and fittings sold in the U.S. market.

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

As a Green Chemistry Alliance (GCA) Coalition member, we appreciate the extensive effort DTSC has once again invested in its latest effort to develop a regulatory system that fulfills the Director's stated objective of being meaningful, practical, and legally defensible. PMI endorses and supports the comments being submitted by the GCA including the Alliance's Key Issues of Concern document. We acknowledge that changes we deem as improvements have are embodied in the subject revised proposed regulation. Some of the more significant improvements include:

- Adding language that explicitly states nothing in the regulation authorizing DTSC to supersede the requirements of any other California, state or federal regulatory program;

- Identifying the initial list of roughly 1,200 chemicals derived from 23 lists as “Candidate Chemicals” instead of “Chemicals of Concern.” This is a positive change that incorporates feedback from the regulated community, taking into account the use, nature and extent of the exposure(s) in identifying human health or environmental safety concerns;
- Retaining a more focused subset of 230 Candidate Chemicals for the outset of the program through 2016; said chemicals to be selected on the basis of the chemicals’ hazard traits AND exposure characteristics
- Retaining a focused startup for the program by selecting a maximum of 5 Priority Products (PP) containing a designated Chemical(s) of Concern (CoC);
- Requiring future updates to the PP list to be established and updated under the requirements of the Administrative Procedures Act (APA);
- Requiring companies to conduct the Alternatives Analysis, focusing on the CoC and potential replacement chemicals;
- Focusing on a product-chemical combination as the PP, thereby decreasing the likelihood of a regulatory treadmill for a product that no longer contains the designated CoC;
- Limiting the requirement to submit a revised Alternatives Analysis Report only if a selection of decision changes and only within three years of DTSC approving a final Alternatives Analysis Report;
- Limiting the basis for, and application of, regulatory responses to the CoCs in any PP and any replacement chemicals on the Candidate Chemicals list; and
- Removal of concept of certified assessors and accreditation bodies.

While these provisions are largely seen as positive and responsive to industry concerns and comments, when viewed as a package where each piece builds upon another, the positive ramifications are either voided or offset by other more onerous provisions.

**For instance, the single most important provision to ensuring a workable program, PMI urges the Department to revise its latest approach on the use of the Practical Quantification Limit (PQL) as the threshold for an Alternatives Analysis exemption.** DTSC’s decision to utilize the PQL as a threshold value effectively eliminates the concept of *de minimis* as a consideration, despite including reference to “intentionally added” and “contaminant,” resulting in an unworkable regulation for businesses.

As a coalition member, we have presented *de minimis* language on multiple occasions, and variations thereof, that would establish a default level consistent with other national and international regulatory jurisdictions while still allowing DTSC discretion to set a lower or higher *de minimis* value on a case specific basis as scientific information warrants.

In yet another attempt to find middle ground on the issue with the Department, we suggest DTSC retain the PQL consideration for contaminants and unintentionally added substance BUT at the same time allow manufacturers to prepare a safety case demonstrating the safety of a product/COG combination. PMI urges DTSC to revise the proposed rule to enable manufacturers to demonstrate the safety of specific product/chemical combinations, as necessary. Neither should the regulations, nor DTSC, presume that the mere presence of an identified Candidate Chemical or CoC is reason to suggest potential harm. If manufacturers can demonstrate the safety of their product, the product should not be required to complete the AA process.

In addition to the PQL issue, PMI wishes to reiterate many of the serious concerns that we've raised time and time again which we continue to believe will keep the SCP program from being implemented as a deliberate science-based effort that focuses on actual public health and environmental safety associated with commonly thought of consumer products. We are highly concerned that the revised proposed regulatory framework:

- Will be impractical and unworkable, in many situations bordering on arbitrary decision making and the stifling of innovation;
- Will impose unnecessary costs and administrative requirements on companies;
- Continues to suggest that DTSC has the discretion to determine whether a product-chemical combination should be subject to the regulation when the statute specifically provides a prohibition against superseding the authority of other state and federal regulations;
- Eliminates an upfront exemption for products in the supply chain of statutorily exempted products, particularly as DTSC does not have the authority to regulate the supply chain of exempted products and such action would be considered superseding the authority of another agency;
- Continues to provide for a "narrative" product-chemical prioritization process that could lead to focusing on product-chemical combinations that will provide little or no meaningful improvement in public health and the environment;
- Changes the word "impacts" to "effects" effectively subordinating exposure to hazard. The language of the enabling statute is quite clear on this issue and chooses the word "impacts" on eleven (11) occasions. As NGOs have argued for the restoration of the word "potential" over the word "ability," PMI calls upon DTSC to restore the use of the word "impacts."
- Fails to include an opportunity for a manufacturer to demonstrate the safety of a priority product through an analysis of and exposure to the chemical from product use and disposal;
- Fails to adequately protect trade secrets, such as chemical identities, and presumes that patents are sufficient to protect a company's intellectual property;
- Provides for a public comment process on all Final AA Reports, particularly with this being a regulatory program whereby the review should be the responsibility of DTSC;
- Provides inadequate timelines, fails to adequately consider consumer acceptance, has limited economic feasibility criteria and requires an external economic impact analysis for conducting alternatives analyses; and
- Requires manufacturers to provide a listing of all retail sales outlets in the Alternatives Assessment reports, which is clearly proprietary information that goes beyond DTSC's statutory authority.

These concerns, while not exhaustive, not only question the practicality, meaning, and legality of the regulation, but also raise issues regarding the necessity, clarity, and consistency of various components of the regulation.

The Department has opted to focus the program initially by identifying up to five Priority Products. While this is a practical approach that will enable the Department to conduct an orderly startup, learn what works and does not work, and make adjustments accordingly; it is not a panacea. Identification and prioritization of a single

product-chemical combination could result a multitude of individual brands as well as domestic and non-domestic manufacturers being responsive to the regulation. Most perplexing is that virtually all commercially available products and their packaging will be subject to the regulation, not simply common everyday consumer products. This will certainly lead to arbitrary selections and decisions based on qualitative rather than quantitative information. As a consequence 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.

PMI and its GCA coalition members strongly support the noted improvements, but continue to have serious concerns with the proposed regulation as revised. We appreciate your consideration of our concerns

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

Sincerely,



**Len Swatkowski**

Technical Director

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PMI members include: American Standard Brands, Inc. \* Amerikam, Inc. \* Bradley Corporation \* BrassCraft Mfg. Co. \* Chase Brass & Copper Company \* CSA International \* Delta Faucet Company \* Dornbracht Americas \* Duravit USA \* Elkay Manufacturing Company \* Fisher Manufacturing Company \* Fluidmaster, Inc. \* Hansgrohe, Inc. \* International Association of Plumbing and Mechanical Officials \* InSinkErator \* Kohler Company \* KWC America, Inc. \* Lavelle Industries \* LSP Products \* Moen Incorporated \* Mueller Brass Company \* NEOPERL, Inc. \* Pfister \* Sloan Valve Company \* Speakman Company \* Symmons Industries Inc. \* T & S Brass and Bronze Works, Inc. \* TOTO USA \* Vitra USA \* Water Pik \* WCM Industries, Inc.



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February 28, 2013

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

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

**Re: Safer Consumer Product Alternatives Regulation, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations (Z-2012-0717-04) (January 29, 2013)**

Dear Ms. Von Burg:

The Procter & Gamble Company (P&G)<sup>1</sup> appreciates this opportunity to comment on the proposed Safer Consumer Product Alternatives Regulation<sup>2</sup> ("proposed regulation") released on January 29, 2013, by the California Department of Toxic Substances Control ("DTSC" or "Department") for the implementation of AB 1879 (Feuer, 2008) and SB 509 (Simitian, 2008). Additionally, P&G has filed comments on all prior iterations of the proposed regulation, including the most recent July 2012 proposal, which we incorporate by reference.

### **General Comments**

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

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

<sup>2</sup> <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCP-Revised-Text.pdf>

Director Raphael has often described her vision for creating a regulatory program to implement the Green Chemistry Initiative as one that is “practical, meaningful and legally defensible.” We see evidence of this vision in the following positive provisions of the proposed regulation:

- The Department’s decision to initially focus implementation of the program on an identified small collection of (up to five) Priority Products and to limit the Alternatives Assessment (AA) requirements and regulatory actions on the Chemical of Concern in the Priority Product. This is a practical and targeted approach that will enable the Department to start small and learn over time with this unique program, to make adjustments according to what works and what does not work, and to focus the compliance efforts of the responsible entities.
- The requirement that future updates to the final Priority Product list take place under the proceedings of the Administrative Procedures Act (APA).
- We also applaud the Department for removing the certified assessor requirement in this proposal. We believe the Department made this decision in recognition of the impracticality in finding unbiased, third party certifiers with the full breadth of education and experience needed to review and meaningfully critique a manufacturer’s Alternatives Assessment report for a unique consumer product technology.

While we commend the Department for these positive revisions in the proposed regulation, we remain discouraged that the clear persuasion in the proposed regulation is for substitution with a “safer” alternative as an outcome of the Alternative Assessment process. A regulation structured in this way fails to appropriately recognize and implement the more holistic, risk-based approach outlined in AB 1879. The hazard-based focus of the proposed regulation obviates all of the positive, practical revisions by creating a command-and-control regulatory framework that provides no guarantee of meaningful improvements to public health and environmental protection.

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

P&G was an early supporter of the genesis of the California Green Chemistry Initiative, and over the last 5 years we've freely shared with DTSC our formulary and life cycle scientific expertise to help shape its implementation. Our commitment to this effort grew from a core belief that, if implemented correctly, this program would firmly position California (and the United States) as a global leader of sustainable innovation and evolved chemical management.

We believe that a very different outcome will emerge from implementation of the current proposed regulation than the optimistic vision from which this journey began. Instead of California leading the world as the entrepreneurial birthplace of sustainable innovation, the state will likely trail other geographies in the competitive global marketplace due to the slow emergence of technology that can successfully navigate the complex regulatory environment. Further, the economic impact this regulation will have on California businesses and manufacturers who sell to California consumers is uncertain because of the broad scope and untested provisions. This uncertainty does not bode well for California during this period of slow economic recovery and sharply contrasts with the original promise of the California Green Chemistry Initiative.

### **Recommendations**

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

While we fully support the comprehensive comments submitted by the aforementioned trade associations, we have elected to focus our P&G comments on select considerations that we believe are most critical to a workable regulation. We strongly recommend that DTSC incorporate the following elements in further refinement of the proposed regulation:

**Implement a more focused program concentrating on the substances in consumer products that pose true risks for human health and the environment, based on a risk-based evaluation of hazard, exposure and the likelihood of harm.** This approach will deliver the meaningful results of Director Raphael's vision by achieving measureable improvements in public health and environmental benefit. The risk-based approach will focus DTSC's limited resources on opportunity areas and yield the best overall outcome for California in terms of meaningful results and economic impact.

**Create regulatory certainty for the business community by establishing a practical *de minimis* threshold for presence of a Chemical of Concern in a Priority Product.** An established *de minimis* threshold provides certainty and predictability to the business community in terms of their compliance responsibilities. Without

a *de minimis* threshold, manufacturers are left confused as to whether they or their brands are within scope of the regulatory compliance obligations, forcing manufacturers to conduct unnecessary and expensive testing to detect trace chemical presence that has no bearing on objective safety but may tip them into compliance scope.

P&G has consistently advocated for the inclusion in the proposed regulation of a 0.1% *de minimis* threshold for intentionally-added Chemicals of Concern in Priority Products. The Practical Quantitation Limit (PQL) approach that appears in this proposal requires regulatory compliance for Chemicals of Concern at detection levels in a Priority Product. With continuously improving analytical capability and ever-lower detection limits, analytical labs can identify small and insignificant levels of trace chemical presence in consumer products. The exposure to such trace chemicals is infinitesimal at best; the control of which is meaningless in protecting public health. Threshold provisions are standard in a variety of international chemical and product safety laws. We strongly encourage California to remain consistent with other national and international laws that recognize the logic that the low, but measurable, levels in consumer products do not create significant exposures that present a likelihood of harm. While a 0.1% *de minimis* provides a default threshold, we fully support flexibility for DTSC to adjust the default *de minimis* based on sound science and reliable information, which is an allowance practiced presently in the European Classification system (EC No. 1272/2008).

**Allow manufactures to demonstrate the safety of specific Chemical of Concern/Priority Product combinations.** Mere presence of a Chemical of Concern in a Priority Product does not equate to likelihood of harm. If a manufacturer can demonstrate that there is no significant risk of harm from exposure of consumers or the environment to the Chemical of Concern during manufacturing, use and disposal of the Priority Product, DTSC should not require the Alternatives Assessment.

We recommend that DTSC add an explicit mechanism in the APA process that authorizes the manufacturer to provide DTSC information about the hazards and exposures of the product to demonstrate the product's safety through manufacturing, use and disposal. Creating such an opportunity could provide the Department with previously unknown information to alter the product prioritization decision and/or make compliance with the AA requirements unnecessary by showing that the Priority Product is safe for humans and the environment. **We recommend that DTSC add a process in 69503.5(b) which enables manufacturers to submit - and requires DTSC to review - a product safety rationale as to why a particular product/chemical combination should not be a Priority Product and need not continue into Alternatives Assessment.**

**Do not eliminate trade secret protections by the regulation.** The importance of robust trade secret protection to a functioning, competitive marketplace cannot be overstated. We implore DTSC to significantly strengthen the trade secret provisions in the proposed regulation. The proposed regulation, as currently constructed, diminishes the important trade secret protections provided under the California Civil Code.

Under the California law, a manufacturer has trade secret protection for all non-publicly disclosed information from which the manufacturer derives or may derive an economic advantage. The manufacturer has the right to stop others from misappropriating (including disclosing or using) its trade secrets for as long as reasonable measures are taken by the manufacturer to maintain the information as a secret. Trade secret protection is

lost if the information becomes publicly available through public disclosure by the manufacturer (including by a patent publication) or otherwise becomes generally known to the public by means permitted under the law (e.g., by reverse engineering).

We strongly oppose the proposed regulation's refusal to allow manufacturers to protect as a trade secret the identity of a chemical that is the subject of a hazard trait submission only if a patent application is pending and then only until "the patent application has been granted or denied". There is no requirement under the California law for the owner of a trade secret to seek patent protection in order to obtain or maintain trade secret protection. This is because the California trade secret law recognizes that trade secrets are a legally protected alternative to seeking patent protection. The proposed regulation therefore takes away a right otherwise permitted under California law.

Most companies rely on a combination of trade secret and patent protection in order to protect their technologies and inventions. Some examples of situations where a manufacturer might want to or needs to choose trade secret protection instead of patent protection for a chemical subject to a hazard trait submission are: the chemical is not new and therefore patent protection is not available; the life of the trade secret protection is likely to be longer than the 20 year patent term (as would be the case if the chemical is hard to reverse engineer and therefore sale of the product would not terminate trade secret protection); and, where reverse engineering is not likely, the risk of teaching competitors by the United States patent publication how to use the chemical in products sold outside the United States (where the U.S. patent provides no protection, and where local patent rights are weak or non-existent) outweighs the benefit of obtaining a U.S. patent.

As we have discussed in previous written comments, chemical identities are often a core trade secret, the disclosure of which is unnecessary considering that the public can interpret hazard trait information independent of a specific chemical identity. We fully support comments provided by the American Chemistry Council that discuss the sufficiency of generic chemical names in association with hazard trait information to meet statutory requirements and to enable an appropriate level of information to the public for understanding the safe use of chemicals.

Finally, we oppose public review of manufacturers' AA reports as the Department's approach to quality assurance. Substantial portions of a manufacturer's AA report will require trade secret protection. Detailed, data-based comparisons of Chemical(s) of Concern and potential alternatives will reveal how those ingredients interact with the formula matrix to deliver desired results. This is key information that, when disclosed by DTSC for public review during program implementation, will decode confidential formulary science to competitors.

DTSC has a host of regulatory responses at its disposal to ensure that AAs are properly conducted. Nevertheless, should the Department remain intent on pursuing some form of public quality control over the AA process, we request the development of standards for the types of public comments that require a formal response from the manufacturer. Requiring a manufacturer to review and respond to every public comment would result in a cumbersome and resource-intensive process without additional benefits. The manufacturer needs the ability to dismiss non-science based comments that are not relevant to the final AA.

\* \* \*

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

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

Sincerely,

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**Statement by the Professional Beauty Association  
February 28, 2013**

**California Department of Toxic Substances Control  
Safer Consumer Product Alternatives**

**RE: Revised Proposed Safer Consumer Products Regulations Issued January 29, 2013**

The Professional Beauty Association (PBA) is a non-profit trade association that represents the interests of the professional beauty industry in the United States. PBA is the largest organization of salon professionals with members representing salons and spas, distributors, manufacturers and beauty professionals.

The professional beauty industry is an important component of the economy of California and the United States representing more than 900,000 total establishments and annual sales of nearly \$40 billion nationwide generated in large part by small businesses.

Of over 758,000 Hairdressers, Hair Stylists and Cosmetologists, 34 percent (or 260,000) are self-employed with Barbers comprising the highest percentage at 49 percent. The nation's salon and spa industry provides first jobs and career opportunities for individuals of all backgrounds, and has a broader representation of women and minorities than the overall U.S. workforce. The employment opportunities provided by salons and spas also provide the experience to own their own businesses (Source U.S. Department of Labor Statistics; 2012 data).

PBA has significant concerns with the revised proposed regulations.

As PBA stated in its September 6, 2012 Statement, the DTSC is uncertain about the economic impact of the regulations on businesses both large and small not only in California but throughout the United States and stated it was unable to quantify the economic impact on businesses (45 Day Notice p 27).

DTSC further recognizes that the regulations will affect and reduce jobs in both in-state and out-of state businesses including chemical and product producers, brand name manufacturers, importers and retailers in the supply chain for a Priority Product (45 Day Notice p 27, 29).

The potential adverse economic impact of the proposed regulations has been significantly compounded by DTSC's proposal requiring a company that is seeking trade secret protection to prove that a patent application is pending for the chemical or its contemplated use in the product.

This requirement incorrectly combines two distinct forms of intellectual property in a manner which seriously erodes existing statutory and common law property rights granted to owners of trade secrets and could cause the loss of valuable intellectual property assets key to the viability of their business.

Under state and federal law, a business entity may claim as a trade secret any information that generally (1) is used in one's business (2) has economic value or provides an economic advantage (3) is not generally known, and (4) is not readily ascertainable by others. There is no term to the life of a trade secret, provided it is kept confidential and not disclosed to a third a party.

Patents, on the other hand, require something to be (1) novel, (2) useful, and (3) non-obvious and remain confidential only during the application process. Once a patent is issued and published, it is a public record. Although the holder of the patent retains the sole and exclusive right to use it for 20 years, the term of the patent is nonrenewable. Upon the patent's expiration, anyone can use the subject matter of the patent for commercial purposes.

Companies make strategic business decisions whether to seek trade secret protection or file for patent protection. In many cases, particularly where the discovery or invention is a product formula that cannot be discoverable by analysis or inspection, a company will choose trade secret protection over filing an application for a patent due to the potentially unlimited time it may have an economic advantage in the marketplace obtained from the trade secret.

Consequently, the regulation could force businesses to either waive their trade secret assets, or to take on the considerable expense of preparing, filing, prosecuting and maintaining patent protection over all of their inventions and discoveries, in order to continue to avail itself of its statutory and common law rights governing trade secret protection. It can take years for a patent to be issued and published (if granted).

There is also the problem with foreign competitors gaining access to critically important and valuable trade intellectual secret product formulations and processes. This is a well-recognized international problem for U.S. businesses and aggressively pursued by the federal government.

PBA urges DTSC to revise this provision to ensure the protection of these valuable assets and avoid the significant and perhaps incalculable loss to a business that may occur if those intellectual property rights are lost.

The revised proposed regulation threatens the viability of companies with the loss of their economically invaluable trade secret assets, imposing unnecessary costs and burdens upon these companies, and detrimentally impacting the economies of California and the U.S.

PBA urges DTSC to further revise the regulations to avoid this unintended consequence and to give due consideration to all the science based and economic issues that were raised in comments submitted to DTSC by our industry and the peer reviews on the revised proposed regulations.

To whom it may concern:

I am honored to review and comment on the California's Department of Toxic Substances Control (DTSC) proposed rule on Safer Consumer Products regulation proposed on January 29, 2013. As a concern US citizen residing in California, I have the following comments that would like DTSC to consider in the final rule making process:

- 1) As California is a leading state in the US in environmental and sustainability movement, I believe that DTSC should not diminish our State's authoritative power. For example, California has the most stringent air regulation in reducing pollution emission under AB32 and promulgated CA Air Resources Board (CARB) to implement various regulations to achieve those goals. Such example has set precedence for our State in restricting more concern products on the store shelves that DTSC can regulate under the intent of this proposed Safer Consumer Products regulation. If DTSC allows the current language shown in Title 22 CCR §69501(a)(3)(A), many consumer products will fall outside the purpose of this regulation. For example, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) governs and regulates various pesticides and herbicides in the US. However, the fact that there is not such responsible stewardship program in the end of life management of the unused or left-over pesticides or herbicides. I believe DTSC shall modify the language to include DTSC's reserved right in regulating consumer products that have also been regulated under federal, state and/or local agency(ies). Otherwise, many consumer products in CA commerce will be definitely exempted from this regulation and continue business as usual. The purpose of protecting our environment as well as the well-being of Californians and US citizens will never be achievable. Please consider prudently the chosen language in this Applicability section.
- 2) I greatly appreciate that DTSC leaves most of the End-of-Life Management Requirements (§69506.7) intact and includes the extended producers' responsibilities (i.e. product stewardship) in this section. That would help so much to a responsible, average consumer to find a proper outlet for any unwanted or left-over materials for proper disposal in a more convenient way instead of relying mainly on existing household hazardous waste program or similar take-back programs.
- 3) According to the recent article published online:

<http://resource-recycling.com/node/3557>

DTSC has not done much on the enforcement on various areas under DTSC's oversight jurisdiction. If a perfect regulation is written but enforcement cannot be achieved, I am afraid that DTSC's intent in this regulation would fail as well, even DTSC intends to publicize the non-compliance on DTSC's website (§69501.2) or to stop selling such non-compliance products in CA (§69506.5). Retailers, especially, large businesses, could follow what the article referenced to ignore the wrongdoing and settle on court with fines to continue business as usual. I believe DTSC should consider to include an enforcement section in this proposed regulation.

Thank you very much in taking your time to read and consider my comment. I wish my comment can help our next generation and generations to come without unintended consequences.

Sincerely yours,

Billy Puk